Newborn Screening Quality Assurance Program

2004 ANNUAL SUMMARY REPORT

Volume 22 March 2005

INTRODUCTION

The Newborn Screening Quality Assurance Program (NSQAP) is designed to help screening laboratories achieve excellent technical proficiency and maintain confidence in their performance while processing large volumes of specimens daily. We continually strive to produce certified dried-blood spot (DBS) materials for reference and quality control (QC) analysis, to improve the quality and scope of our services, and to provide immediate consultative assistance. Through our interactive efforts with the program's participants, we aspire to meet their growing and changing needs. We always welcome comments and suggestions on how we may better serve the newborn screening laboratories.

A major public health responsibility, newborn screening for detection of treatable, inherited metabolic diseases is a system consisting of six parts: education, screening, follow-up, diagnosis, management, and evaluation. Effective screening of newborns using DBS specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are collected routinely from more than 98% of all newborns in the United States. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that require intervention. For more than 26 years, the Centers for Disease Control and Prevention (CDC), with its cosponsor, the Association of Public Health Laboratories (APHL), has conducted research on materials development and assisted laboratories with quality assurance (QA) for these DBS screening tests. The QA services primarily support newborn screening tests performed by state laboratories; however, we also accept other laboratories and international participants into the QA program. All laboratories in the United States that test DBS specimens participate voluntarily in NSQAP. The program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, tyrosinemia, citrullinemia, biotinidase deficiency, galactose-1-phosphate uridyltransferase (GALT) deficiency, cystic fibrosis (CF), and hemoglobinopathies. QA services are also provided for urea cycle disorders, fatty acid oxidation disorders, and organic acid metabolic disorders.

The QA program consists of two DBS distribution components: QC materials for periodic use and quarterly proficiency testing (PT). The QC program enables laboratories to achieve high levels of technical proficiency and continuity that transcend changes in commercial assay reagents while maintaining the requisite high-volume specimen throughput. The QC materials, which are intended to supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PT program provides laboratories with quarterly panels of blind-coded DBS specimens and gives each laboratory an independent external assessment of its performance. DBS materials for QC and PT are certified for homogeneity, accuracy, stability, and suitability for all kits manufactured by different commercial sources.

Over the last nine years, NSQAP has grown substantially, both in the number of participants and in the scope of global participation (Figure 1). In 2004, 356 newborn screening laboratories in 53 countries (at least one laboratory per country) were active program participants; of these, 313 participated in the PT component and 239 in the QC part (Figure 2). One hundred eight laboratories participated in the tandem mass spectrometry (MS/MS) PT program. Of these, 39 were domestic laboratories (Figure 3). DBS materials for 24 analytes, including analytes measured for the separate MS/MS program, were

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
and the
Association of Public Health Laboratories

NSQAP
Contents

Program Information Web site:
http://www.cdc.gov/labstandards/nsqap.htm

Data-reporting Web site:
http://www2.cdc.gov/nceh/NewbornScreening

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distributed to participating laboratories (Figures 4-6). This report summarizes all QC data reported in 2004, including the MS/MS QC data for amino acids and acylcarnitine analytes: C2, C3, C4, C5, C5DC, C6, C8, C10, C14, and C16. For biotinidase, GALT, and hemoglobins, QC materials were not distributed because of the limited availability of appropriate blood sources.

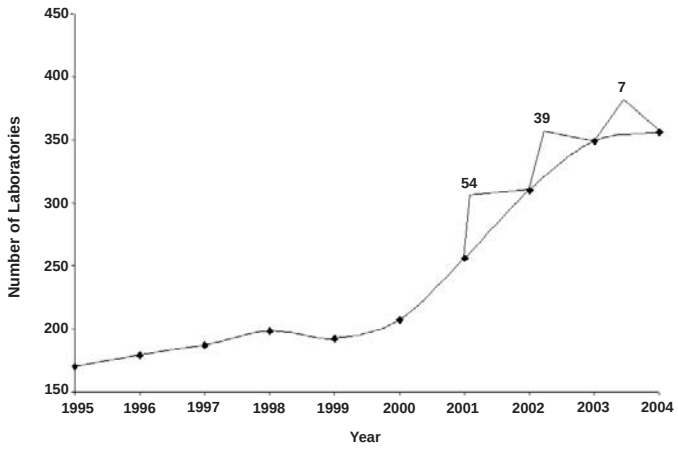
NEW ACTIVITIES

In January and February 2004, NSQAP, APHL, and the National Laboratory Training Network (NLTN) presented a two-part Web conference for *Tandem Mass Spectrometry QC/QA for Newborn Screening* through the Internet. The Web conference presentations are posted for continuing education on the NSQAP Web site at http://www.cdc.gov/labstandards/nsqap.htm.

In 2004, APHL, NSQAP, and the National Newborn Screening and Genetics Resource Center (NNSGRC) cosponsored a 5-day training course, *Newborn Screening by Tandem Mass Spectrometry: A Course in Understanding Laboratory Issues and Interpreting Test Results*, at Duke University Medical Center, Durham, North Carolina, and at Baylor University Medical Center, Dallas, Texas. Twenty-seven laboratorians from 21 states were trained at five workshops. For information about the course, contact Jelili A. Ojodu at jojodu@aphl.org.

A few years ago APHL organized a subcommittee of the Newborn Screening and Genetics in Public Health Committee for QA/QC/PT. One mission component of this subcommittee is to guide the NSQAP on procedures, policies, and activities for QA of laboratory testing. In April 2004, this subcommittee met in Boston to discuss current issues. Input from this subcommittee will

FIGURE 1. Laboratory Participation in the Newborn Screening Quality Assurance Program, 1995-2004



enhance our continuing efforts to better serve our participants.

NSQAP cosponsored the 2004 Newborn Screening and Genetic Testing Symposium, May 3-6, 2004. The conference was held in Atlanta, Georgia, and was preceded by half-day workshops on QA/QC and Follow-Up. Almost 400 laboratorians and follow-up professionals attended.

In May 2004 at the national symposium, Dr. W. Harry Hannon accepted, on behalf of the CDC NSQAP staff, an award plaque from APHL, *In Recognition of 25 Years of Outstanding Service and Dedication to Public Health Laboratory Newborn Screening Programs*. Dr. Hannon also accepted a personal letter of appreciation from United States Senator Christopher J. Dodd offering "congratulations on the 25th Anniversary of the NSQAP which has provided such valuable service nationally and internationally."

In June 2004, CDC implemented new shipping procedures whereby NSQAP can no longer ship by postal service. Our sole shipper is FedEx. Over the last year, Customs clearance of packages to Argentina, Brazil, Colombia, and China has become increasingly difficult.

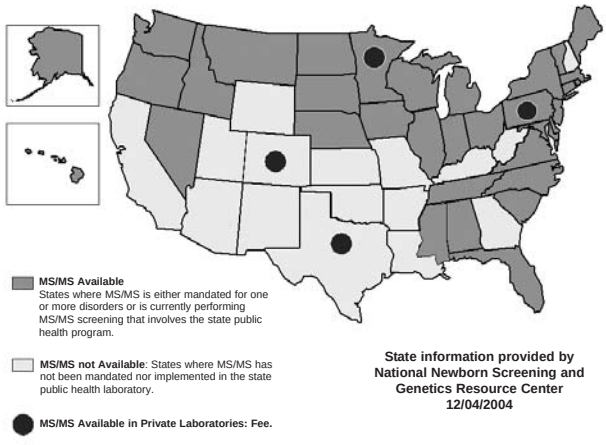
FIGURE 2. Fifty-three Countries Participated in the Newborn Screening Quality Assurance Program in 2004

Participant

Argentina	Greenland	Portugal
Australia	Guatemala	Russia
Austria	Hungary	Saudi Arabia
Belgium	Iceland	South Africa
Brazil	India	South Korea
Canada	Ireland	Spain
Chile	Italy	Sweden
China	Japan	Switzerland
Colombia	Latvia	Taiwan
Costa Rica	Lebanon	Thailand
Cuba	Lithuania	Turkey
Czech Republic	Luxembourg	Ukraine
Denmark	Malaysia	United Arab Emirates
Estonia	Mexico	United Kingdom
Finland	Netherlands	United States
France	New Zealand	Uruguay
Germany	Philippines	Vietnam
Greece	Poland	

One or more laboratories represented for each country listed.

FIGURE 3. States Using Tandem MS/MS for Newborn Screening



Regrettably, we may lose some participants in those countries because we are not able to get our products to them.

NSQAP provided an extensive PT panel of specimens to qualify laboratories as official testing sites for The Environmental Determinants of Diabetes in the Young (TEDDY) project. This diabetes study will track 8000 newborns at high risk for Type 1 diabetes over a 15-year period.

In 2004, NSQAP and CDC colleagues began to translate the T-cell Recombination Excision Circle (TREC) assay, which was first applied to DBS at the National Institutes of Health to detect severe combined immunodeficiency disorder (SCID), into a high-throughput test for routine newborn screening. SCID is a lethal condition, sometimes called "Boy in a Bubble Disease," that is treatable by transplanting bone marrow stem cells from a normal donor.

C5DC and C10 quality control materials became available in 2004.

Programming of the expansion of the PT data-reporting Web site was completed. Beginning in January 2005, the MS/MS analytes were merged with our overall scheme.

FIGURE 4. Number of Participants in Proficiency Testing Programs, 2004

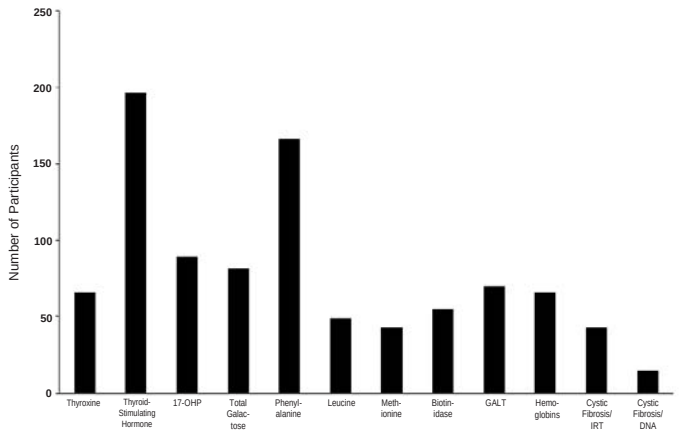


FIGURE 5. Number of Participants in Quality Control Programs, 2004

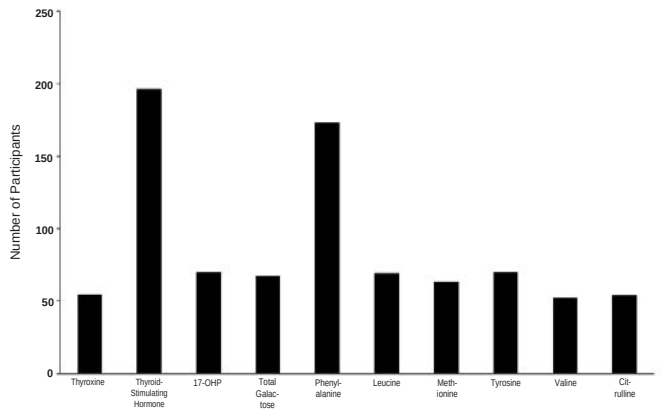
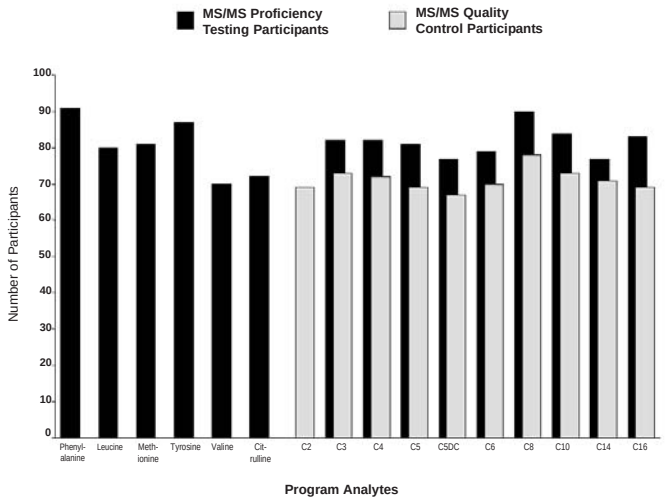


FIGURE 6. Number of Participants in MS/MS-Specific Programs, 2004



Amino acids quality control materials are analyzed by many methods. MS/MS participants are included in Figure 5.

Participants will be able to report results online for a total of 21 analytes.

FILTER PAPER

The paper disk punched to aliquot DBS specimens is a volumetric measurement and requires a degree of uniformity among and within production lots. As part of the QA program, we used an isotopic method[1] developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added isotope-labeled thyroxine (T_4) within a 1/8-inch disk were equated with the serum volume of the disks from the dried whole blood specimens. In comparing production lots, we used statistical analyses of the counting data to determine values for homogeneity and serum absorption of the disks. Lysed-cell whole blood was used initially to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Filter paper evaluation studies conformed by using the same lysed-cell whole blood matrix. Results of later studies concluded that RBC lysis occuring during processing of the intact blood pools was not sufficient to contribute substantially to the variance. However, the mean serum volume per disk differs with intact-cell blood. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure. We also measure performance with intact-cell preparations. The published and standardized acceptable volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval [CI]) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1] The mean values and CIs are the filter-paper evaluation parameters published in the NCCLS-approved standard.[1] The second mean value (solid line) is the mean value produced from the NSQAP database, which was added for reference (Figures 7 and 10). The mean values for all lots are within the 95% CI defined by NCCLS but are below the mean values indicated by the NCCLS standard.[1] In 2002, the mean value and CI for the intact-cell measurements were examined and discussed during a routinely scheduled review period

Laboratory participation has grown 42% in four years.

for revision of the NCCLS standard. The NCCLS committee retained the original values, which were not produced at CDC, in the revised standard.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2004 were W001 and W011 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the NCCLS-approved standard.[1]

Each year, with the extensive cooperation of manufacturers (Schleicher & Schuell and Whatman) of filter papers approved by the Food and Drug Administration (FDA) for blood collection, we have routinely evaluated new lots and compared new lots with previous lots. The criteria for acceptable performance are the approved limits established in the NCCLS standard.[1] Each manufacturer also is expected to establish its own testing program using the NCCLS standard and make available to the user its certification data for each distributed lot of paper. The independent evaluations by CDC are an impartial and voluntary service offered as a function of our QA program and do not constitute preferential endorsement of any product over other specimen collection papers approved by the FDA.

The serum-absorbance volumes of 21 lots of Grade 903 filter paper (Schleicher & Schuell, Keene, NH) determined from lysed RBCs and for 11 lots determined from intact RBCs, are shown in chronological order. For W041, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume was 1.35 µL for a 1/8-inch disk for lysed-cell blood and 1.44 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W041 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

In 1996, the FDA approved the filter paper, BFC180, produced by Whatman Inc. (Fairfield, NJ) as a blood collection device. CDC evaluated the BFC180 according to the criteria previously described.[1] The serum-absorbance volumes for 11 lots of BFC180 filter paper determined from lysed RBCs and determined from intact RBCs, are shown in chronological order. For 3646, the most recent production lot of BFC180 filter paper, we found the mean serum-absorbance volume was 1.41 µL for a 1/8-inch disk for lysed-cell blood and 1.43 µL per 1/8-inch disk for intact-cell blood. Each mean value was within the acceptable range for the matrix used. Lot 3646 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

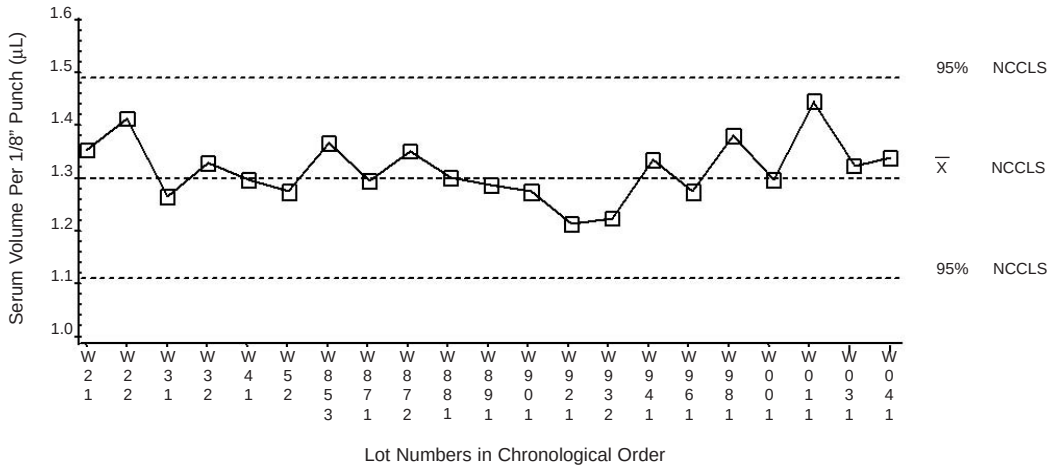
SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot equaled the sum of the enriched concentration and the endogenous concentration (nonenriched). For T_4 PT specimens, the CDC assayed values were reported because of differences in the blood sources used for DBS production. Some specimens were enriched above the endogenous T_4 concentration, and some were enriched with T_4 after T_4 depletion of the base serum. Except for biotinidase and GALT, all DBS specimens in the PT surveys and QC production lots were prepared from whole blood of 55% hematocrit. Purified analytes or natural donor blood, except for thyroid-stimulating hormone (TSH), which used the Second International Reference Preparation (80/558), were used for all enrichments. For galactosemia, enrichments were made with galactose, galactose-1-phosphate, or both so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1-phosphate) could be measured. For biotinidase and GALT, individual donor blood was used. All reported analytic values outside the 99% CI were excluded from the summaries of quantitative results.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2004 were W001 and W011 of Grade 903.

For obtaining data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis to obtain an

FIGURE 7. Schleicher and Schuell Grade 903 Filter Paper Serum Volume by Lot Number - Lysed Red Blood Cells



Schleicher & Schuell

FIGURE 8. Schleicher and Schuell Grade 903 Filter Paper Serum Volume by Lot Number - Intact Red Blood Cells

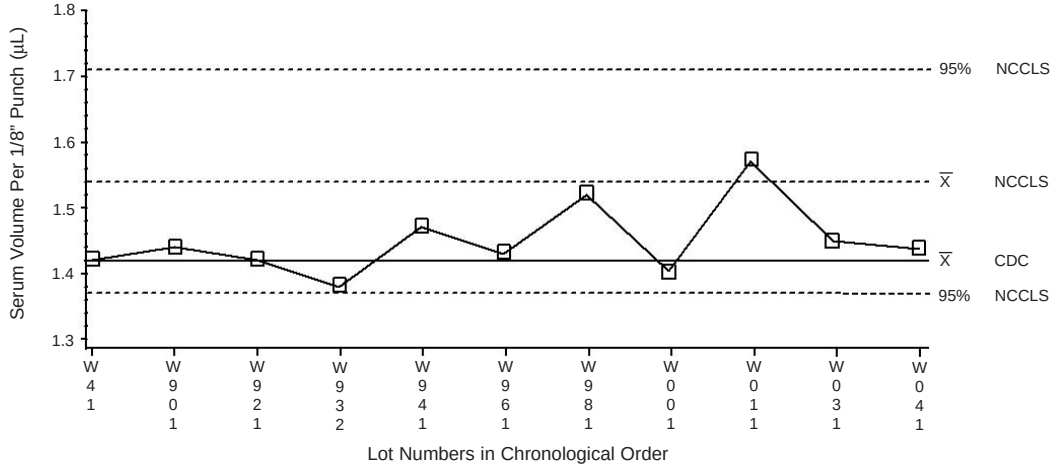
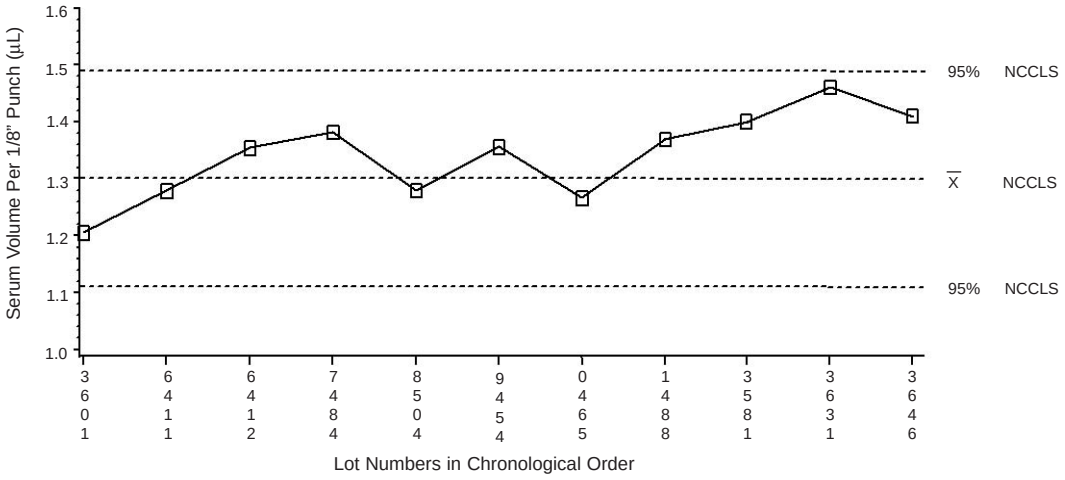
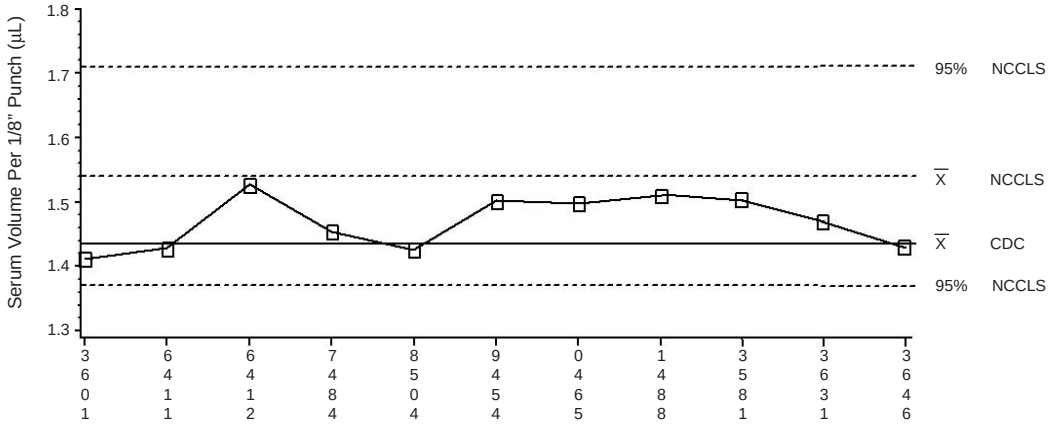


FIGURE 9. Whatman BFC180 Filter Paper
Serum Volume by Lot Number - Lysed Red Blood Cells



Whatman Inc.

FIGURE 10. Whatman BFC180 Filter Paper
Serum Volume by Lot Number - Intact Red Blood Cells



estimate of the observed endogenous analyte concentration for each method category. These estimates are reliable when (1) enrichments are accurate, (2) the analytic method gives a linear response across the range of the measurements, and (3) the slopes for regression lines are approximately equal to one.

In 2004, we applied the laboratory-reported specific cutoff values, when available, to our grading algorithm for clinical assessments; otherwise, we used the NSQAP-assigned working cutoff values based on the national mean value for this assessment.

CUTOFFS

When reporting cutoff values, we requested the decision level for sorting test results reported as presumptive positive (outside limits) from results reported as negative (within limits). The reported cutoff values are summarized in Tables 1 and 2 for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. The mean cutoff values for domestic and foreign laboratories are similar except those for 17 α-hydroxyprogesterone (17-OHP), which are nearly twice as high for domestic laboratories and those for immunoreactive trypsinogen (IRT), which are 30% higher for domestic laboratories. The range (min/max) of cutoff values is large for TSH, 17-OHP, total galactose (Gal), IRT, C3, and C16 for both domestic and foreign laboratories and for all MS/MS amino acids for foreign laboratories. The mean and median of cutoff values for phenylalanine (Phe) are the same for domestic and foreign laboratories; however, the range is larger for foreign laboratories. Mean cutoff values for Phe, methionine (Met), valine (Val), citrulline (Cit), and C5 are almost identical for domestic and foreign laboratories.

TABLE 1. 2004 PT Summary of Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
T4	28	6.1	6.0	6.0	3.5-9.4
TSH	48	31.1	25.0	20.0	19.4-61
17-OHP	30	48.5	50.0	50.0	25-65
Galactose	27	10.8	10.0	10.0	6.5-20
Phenylalanine	50	3.0	3.0	3.3	2-4
Leucine	15	4.1	4.0	4.0	2.1-4.9
Methionine	16	1.4	1.3	1.3	0.8-3
IRT	8	97.3	92.5	90.0	58-170

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
T4	18	6.0	6.0	6.0	3.9-9.7
TSH	113	25.2	22.0	20.0	10-50
17-OHP	42	30.7	22.1	22.0	7-143
Galactose	44	12.3	10.0	10.0	4.5-27.3
Phenylalanine	93	3.1	3.0	4.0	1.3-4.4
Leucine	26	4.8	4.8	3.0	2-8.7
Methionine	22	1.3	1.0	1.0	0.5-4
IRT	23	69.8	70.0	70.0	60-105

PROFICIENCY TESTING

All PT panels contained five blind-coded 75-µL or 100-µL DBS specimens. Specimens in the PT panels either contained endogenous levels or were enriched with predetermined levels of T_4, TSH, 17-OHP, Gal, Phe, leucine (Leu), Met, tyrosine (Tyr), Val, Cit, and acylcarnitines (C3, C4, C5, C5DC, C6, C8, C10, C14, C16). Specimens for the CF panel were prepared with DNA from Epstein-Barr virus-transformed lymphoblastoid cell lines homozygous for ΔF508 in sheep whole blood matrix enriched with IRT. Special separate panels for biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood.

TABLE 2. 2004 MS/MS Summary of Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine Screen	22	2.5	2.4	2.0	2.0-3.6
Leucine Screen	20	4.1	4.1	3.9	3.4-4.9
Methionine Screen	21	1.2	1.3	1.3	0.8-1.5
Tyrosine Screen	17	6.5	6.3	6.1	5.0-9.1
Valine Screen	16	3.6	3.6	3.8	2.9-4.9
Citrulline Screen	18	1.3	1.2	1.8	0.6-1.8
C3 Screen	17	6.85	6.92	8.00	3.30-10.10
C4 Screen	17	1.49	1.44	1.86	0.80-2.50
C5 Screen	16	0.82	0.83	1.00	0.35-1.60
C5DC Screen	15	0.36	0.24	0.21	0.10-1.80
C6 Screen	18	0.52	0.46	0.30	0.17-1.26
C8 Screen	23	0.52	0.50	0.50	0.30-1.00
C10 Screen	18	0.53	0.51	0.51	0.25-0.90
C14 Screen	15	0.79	0.82	0.60	0.26-1.10
C16 Screen	17	8.38	9.00	9.00	0.60-12.00

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine Screen	49	2.5	2.5	2.5	1.0-4.4
Leucine Screen	44	4.4	4.2	3.9	2.1-7.9
Methionine Screen	43	1.3	0.9	1.0	0.4-13.5
Tyrosine Screen	46	5.6	5.5	6.0	2.8-10.9
Valine Screen	42	3.5	3.4	3.5	0.7-11.3
Citrulline Screen	39	1.3	1.1	0.9	0.3-5.3
C3 Screen	44	6.20	5.60	4.00	1.29-19.20
C4 Screen	46	1.27	1.39	1.40	0.40-3.12
C5 Screen	46	0.84	0.68	0.60	0.26-3.30
C5DC Screen	43	0.24	0.20	0.20	0.09-0.66
C6 Screen	42	0.49	0.40	0.30	0.12-2.00
C8 Screen	50	0.43	0.40	0.50	0.16-1.00
C10 Screen	45	0.42	0.40	0.40	0.20-1.00
C14 Screen	44	0.85	0.72	0.50	0.23-4.00
C16 Screen	46	7.79	8.08	8.50	1.38-15.40

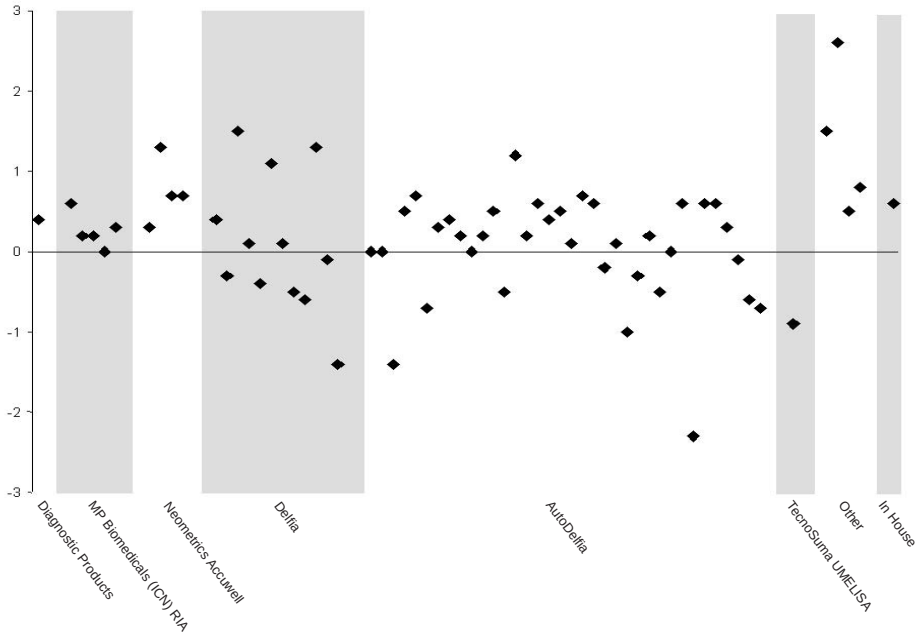
Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms for laboratories that did not report data by Internet. We prepared and distributed quarterly reports of all results that had been received by the cutoff dates. In this annual report, the comparisons of results by different methods (Figures 11-22) are illustrated with the reported PT data for one selected challenge for each analyte during the year. These are compared using bias plots that show the difference (positive or negative) by laboratory and method of the reported value subtracted from the expected value (CDC-measured endogenous level plus enrichment) and for TSH, IRT, or C5DC, the reported value subtracted from the CDC assayed value. When examining the bias plots, note the scale-changes of the Y-axis relative to the expected value for each plot. A reported value matching the expected value will show the illustrated value as falling on the "0" line of the plot. A reasonable bias is less than ± 20% of the expected value. A summary of the specimen data for selected-quarter PT challenges in 2004 is tabulated in the left margin for each figure. All T_4 specimens are enriched with 4.0 µg/dL of T_4 but have different CDC assayed values (Figure 11) because some specimens were prepared from T_4-depleted base pools and others from normal untreated base pools. A base pool is a serum pool prepared by mixing serum from normal donors. The selected normal base pools had different endogenous T_4 levels. This process yields specimens with different values from a common enrichment.

The representative specimens selected for the bias plots (Figures 11-22) were either above or below the cutoff

FIGURES 11-12. Reproducibility of Results by Different Methods - Thyroxine and Thyroid-Stimulating Hormone

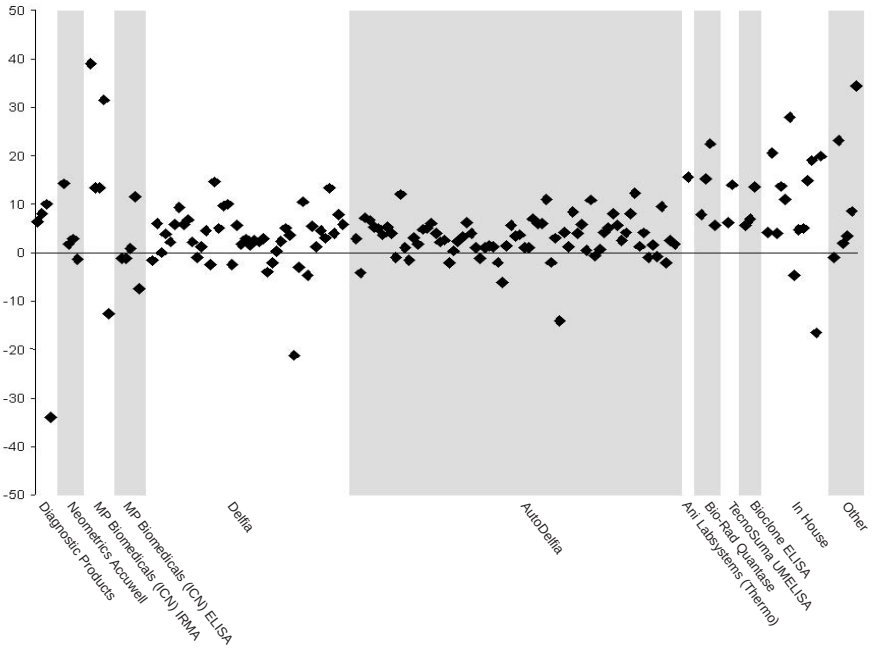
	Quarter 2
Specimen 1	
Enriched	4
CDC Assayed	4.5
Reported Mean	4.6
CDC Bias[2]	0.1
Specimen 2	
Enriched	4
CDC Assayed	11.4
Reported Mean	9.4
Specimen 3	
Enriched	4
CDC Assayed	12.8
Reported Mean	10.5
Specimen 4	
Enriched	4
CDC Assayed	11.6
Reported Mean	10.6
Specimen 5	
Enriched	4
CDC Assayed	13.4
Reported Mean	10.2

Figure 11. Bias Plot of Thyroxine Values by Method
Quarter 2, Specimen 1
Expected Value (EV)[1] 4.4 µg/dL serum



	Quarter 1
Specimen 1	
Enriched	10
CDC Assayed	6
Reported Mean	10.7
Specimen 2	
Enriched	70
CDC Assayed	78
Reported Mean	79.6
Specimen 3	
Enriched	60
CDC Assayed	62
Reported Mean	68.6
Specimen 4	
Enriched	9
CDC Assayed	11
Reported Mean	13.0
Specimen 5	
CDC Assayed	34.0
Reported Mean	38.2

Figure 12. Bias Plot of Thyroid-Stimulating Hormone Values by Method
Quarter 1, Specimen 5
Assayed Value (AV)[3] 34.0 µIU/mL serum

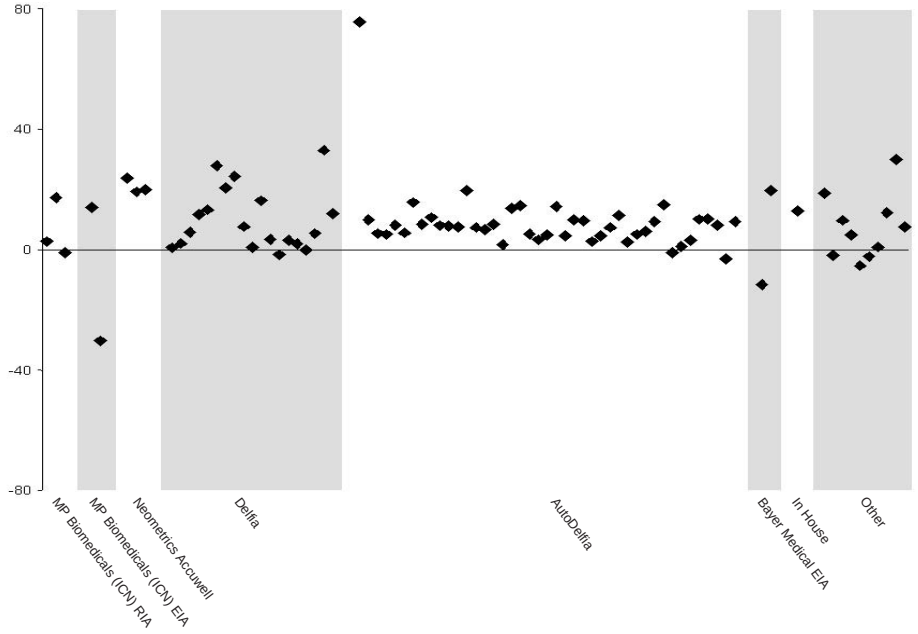


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.
[3]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 13-14. Reproducibility of Results by Different Methods - 17 α-Hydroxyprogesterone and Total Galactose

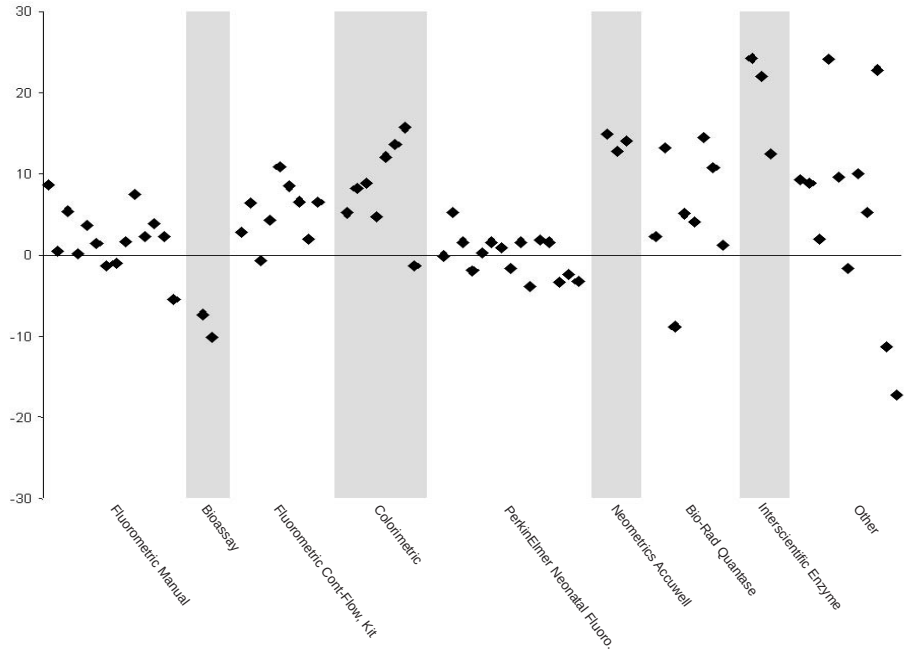
	Quarter 1
Specimen 1	
Enriched	30
CDC Assayed	30.5
Reported Mean	38.6
CDC Bias[2]	0.2
Specimen 2	
Enriched	5
CDC Assayed	5
Reported Mean	8.2
Specimen 3	
Enriched	0
CDC Assayed	0.2
Reported Mean	0.6
Specimen 4	
Enriched	75
CDC Assayed	83.5
Reported Mean	98.4
Specimen 5	
Enriched	0
CDC Assayed	0.4
Reported Mean	0.9

Figure 13. Bias Plot of 17 α-Hydroxyprogesterone Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 30.3 ng/mL serum



	Quarter 1
Specimen 1	
Enriched	21
CDC Assayed	22.1
Reported Mean	25.9
CDC Bias[2]	0.8
Specimen 2	
Enriched	0
CDC Assayed	0.3
Reported Mean	2.5
Specimen 3	
Enriched	0
CDC Assayed	0
Reported Mean	2.7
Specimen 4	
Enriched	0
CDC Assayed	0
Reported Mean	2.4
Specimen 5	
Enriched	29
CDC Assayed	34.3
Reported Mean	38.1

Figure 14. Bias Plot of Total Galactose Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 21.3 mg/dL whole blood

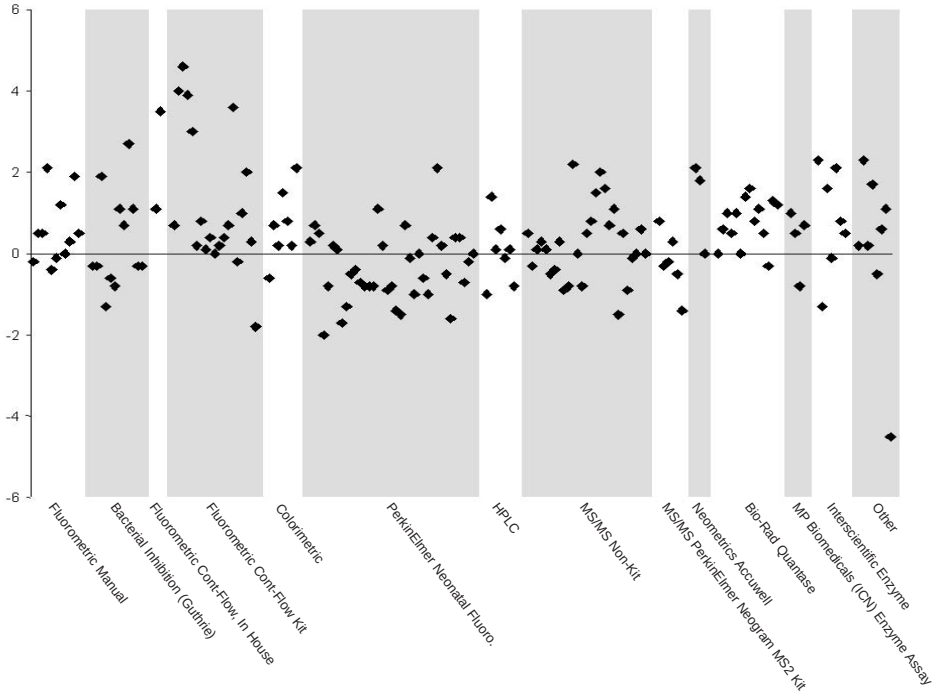


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.

FIGURES 15-16. Reproducibility of Results by Different Methods - Phenylalanine and Leucine

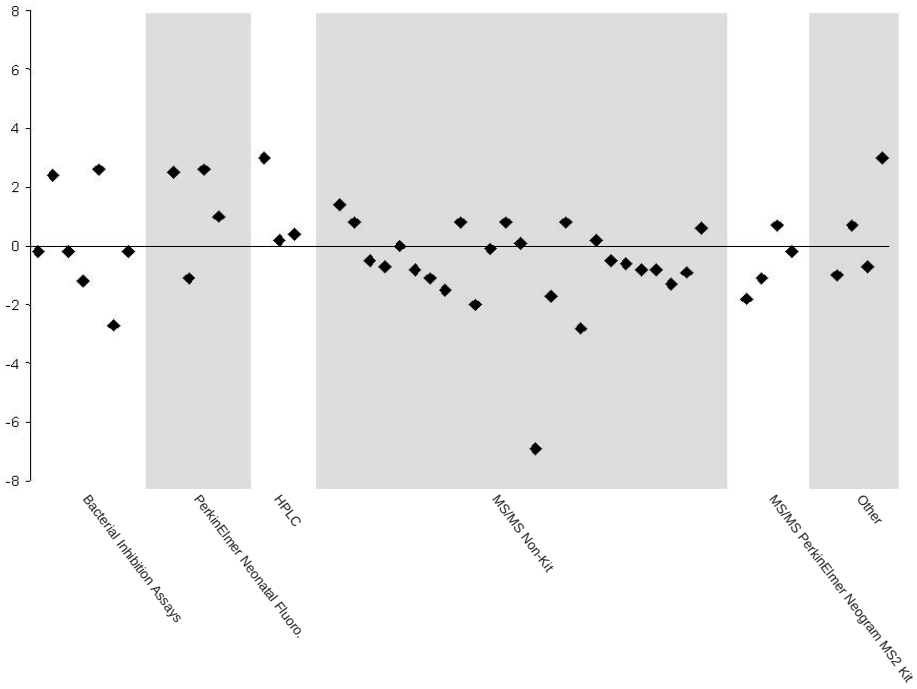
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.3
Reported Mean	0.6
Specimen 2	
Enriched	5
CDC Assayed	7.2
Reported Mean	6.6
CDC Bias[2]	0.9
Specimen 3	
Enriched	0
CDC Assayed	1.6
Reported Mean	1.5
Specimen 4	
Enriched	0
CDC Assayed	1.1
Reported Mean	1.2
Specimen 5	
Enriched	0
CDC Assayed	1.6
Reported Mean	1.6

Figure 15. Bias Plot of Phenylalanine Values by Method
Quarter 2, Specimen 2
Expected Value (EV)[1] 6.3 mg/dL whole blood



	Quarter 1
Specimen 1	
Enriched	5.5
CDC Assayed	5.7
Reported Mean	7.2
CDC Bias[2]	-1.5
Specimen 2	
Enriched	0
CDC Assayed	1.8
Reported Mean	1.2
Specimen 3	
Enriched	0
CDC Assayed	1.4
Reported Mean	1.4
Specimen 4	
Enriched	0
CDC Assayed	2.3
Reported Mean	2.7
Specimen 5	
Enriched	6.3
CDC Assayed	9.1
Reported Mean	7.4

Figure 16. Bias Plot of Leucine Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 7.2 mg/dL whole blood

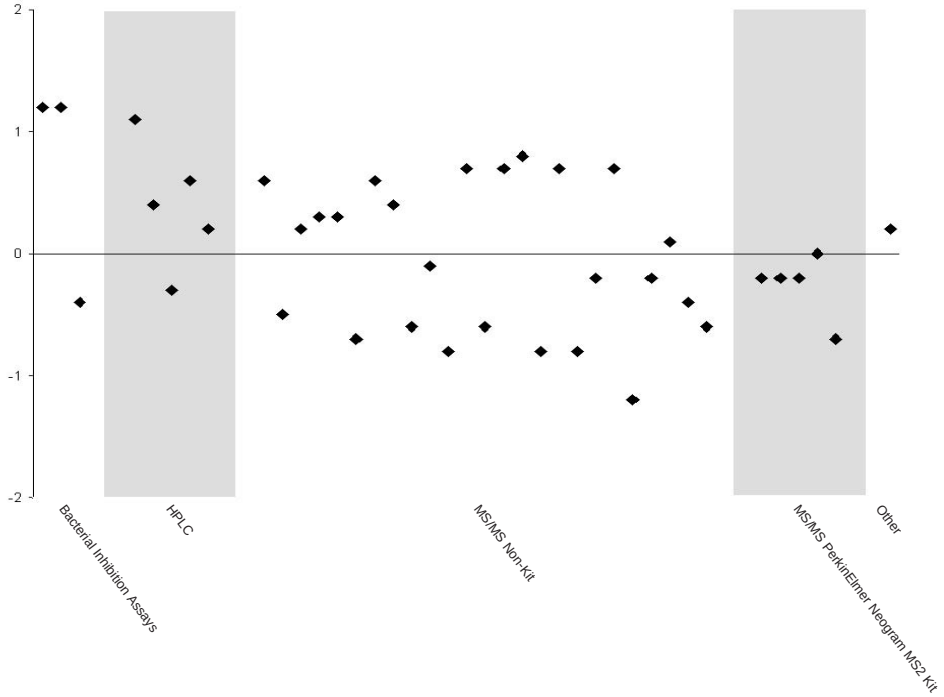


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.

FIGURES 17-18. Reproducibility of Results by Different Methods - Methionine and Cystic Fibrosis (IRT)

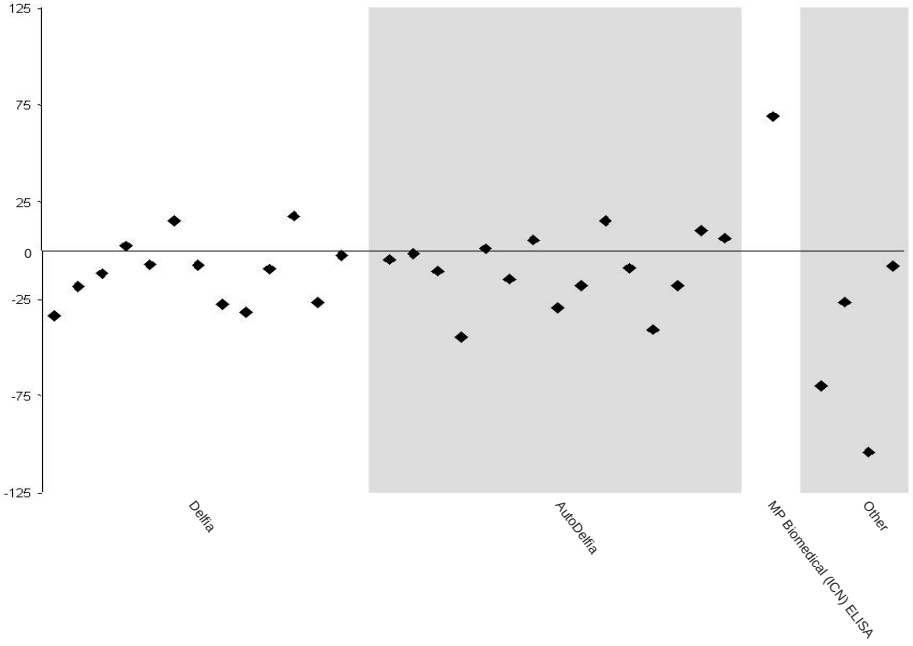
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.1
Reported Mean	0.1
Specimen 2	
Enriched	0
CDC Assayed	0.3
Reported Mean	0.4
Specimen 3	
Enriched	2.5
CDC Assayed	2.7
Reported Mean	2.9
Specimen 4	
Enriched	3.5
CDC Assayed	3.9
Reported Mean	3.8
CDC Bias[2]	0.1
Specimen 5	
Enriched	0
CDC Assayed	0.3
Reported Mean	0.3

Figure 17. Bias Plot of Methionine Values by Method
Quarter 2, Specimen 4
Expected Value (EV)[1] 3.8 mg/dL whole blood



	Quarter 1
Specimen 1	
CDC Assayed	36.2
Reported Mean	37.8
Specimen 2	
CDC Assayed	358.6
Reported Mean	346.4
Specimen 3	
CDC Assayed	157.4
Reported Mean	144.7
Specimen 4	
CDC Assayed	15.9
Reported Mean	14.0
Specimen 5	
CDC Assayed	210.5
Reported Mean	216.2

Figure 18. Bias Plot of Cystic Fibrosis (IRT) Values by Method
Quarter 1, Specimen 3
Assayed Value (AV)[3] 157.4 ng/mL whole blood

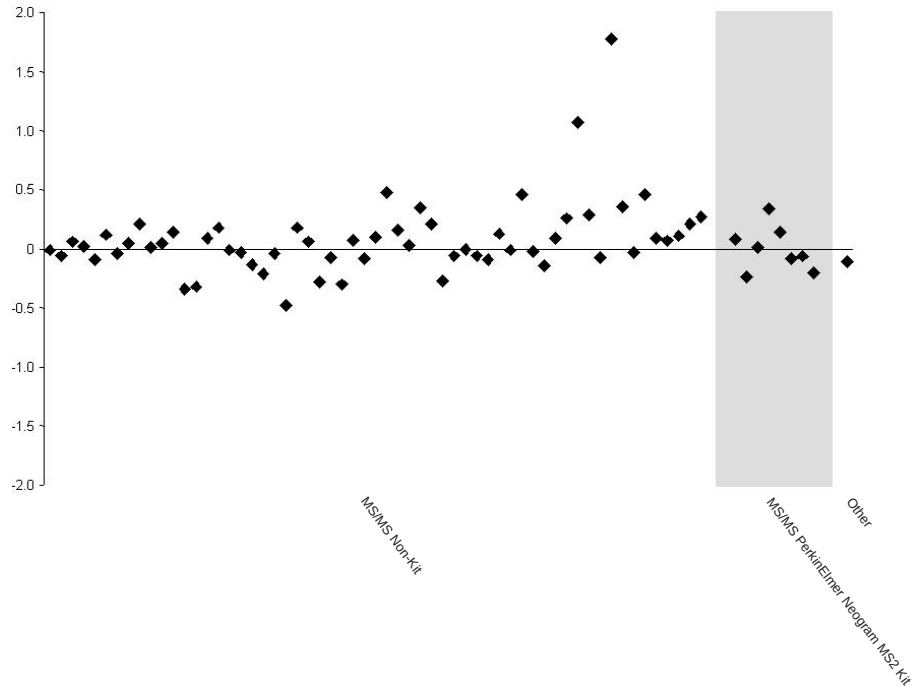


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.
[3]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 19-20. Reproducibility of Results by Different Methods - Octanoylcarnitine (C8) and Decanoylcarnitine (C10)

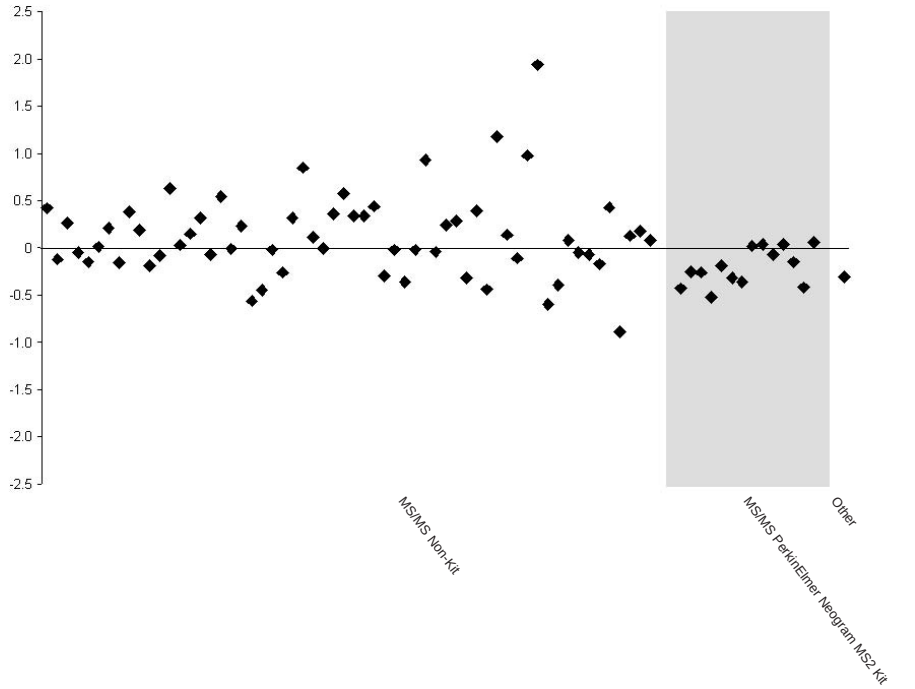
	Quarter 1
Specimen 1	
Enriched	12.40
CDC Assayed	11.31
Reported Mean	11.77
Specimen 2	
Enriched	0
CDC Assayed	0.07
Reported Mean	0.11
Specimen 3	
Enriched	1.00
CDC Assayed	0.97
Reported Mean	1.05
CDC Bias[2]	-0.05
Specimen 4	
Enriched	0
CDC Assayed	0.08
Reported Mean	0.10
Specimen 5	
Enriched	0
CDC Assayed	0.14
Reported Mean	0.07

Figure 19. Bias Plot of Octanoylcarnitine (C8) Values by Method
Quarter 1, Specimen 3
Expected Value (EV)[1] 1.02 µmol/L whole blood



	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.13
Reported Mean	0.14
Specimen 2	
Enriched	0
CDC Assayed	0.05
Reported Mean	0.07
Specimen 3	
Enriched	1.10
CDC Assayed	1.59
Reported Mean	1.23
CDC Bias[2]	0.37
Specimen 4	
Enriched	0
CDC Assayed	0.12
Reported Mean	0.11
Specimen 5	
Enriched	0
CDC Assayed	0.14
Reported Mean	0.13

Figure 20. Bias Plot of Decanoylcarnitine (C10) Values by Method
Quarter 2, Specimen 3
Expected Value (EV)[1] 1.22 µmol/L whole blood

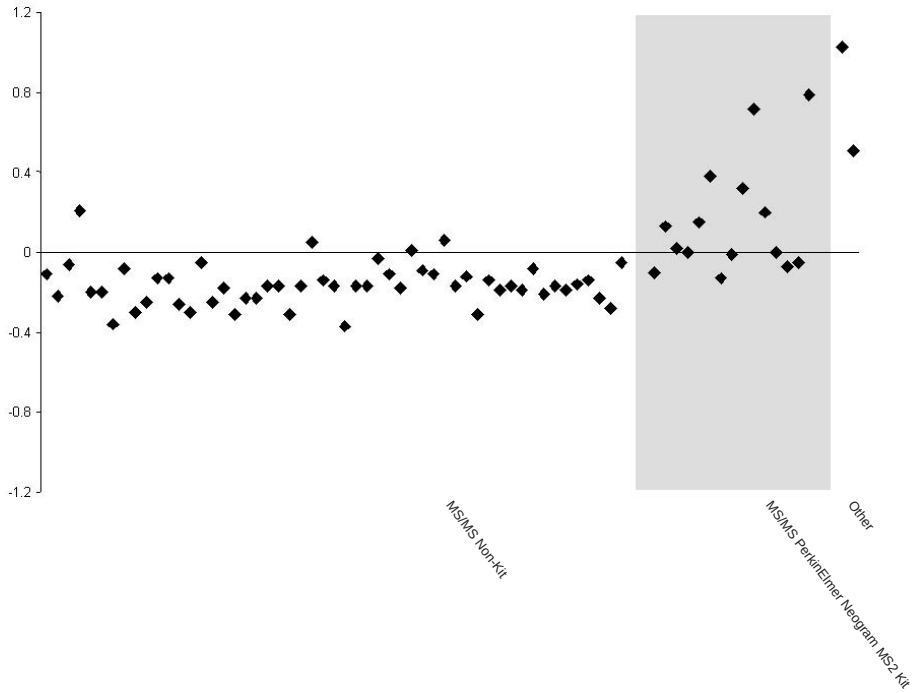


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.

FIGURES 21-22. Reproducibility of Results by Different Methods - Glutarylcarnitine (C5DC) and Citrulline

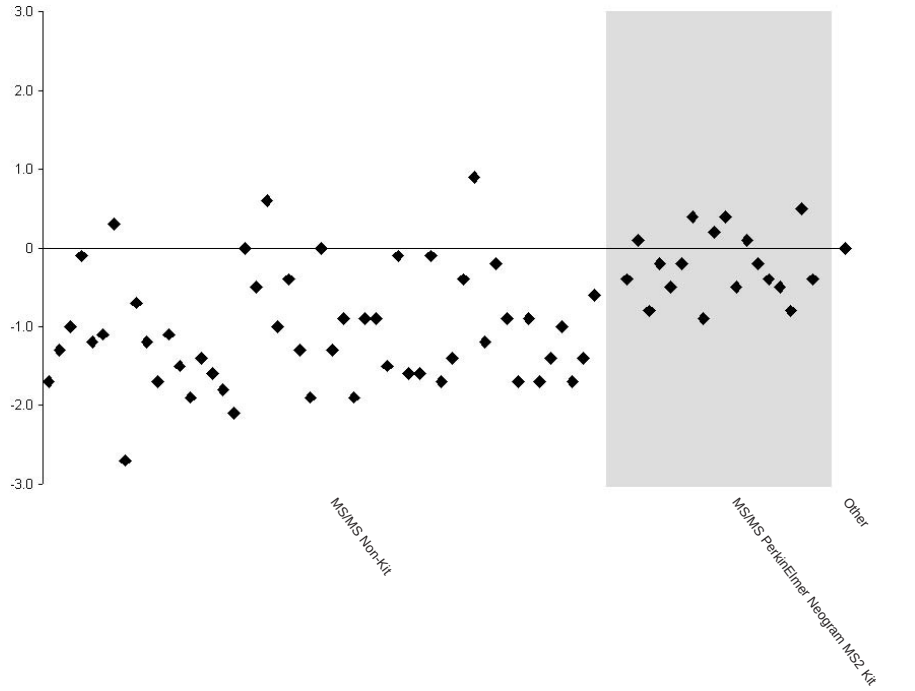
	Quarter 3
Specimen 1	
CDC Assayed	0.78
Reported Mean	0.61
Specimen 2	
CDC Assayed	0.08
Reported Mean	0.07
Specimen 3	
CDC Assayed	0.03
Reported Mean	0.03
Specimen 4	
CDC Assayed	0.42
Reported Mean	0.30
Specimen 5	
CDC Assayed	0.08
Reported Mean	0.05

Figure 21. Bias Plot of Glutarylcarnitine (C5DC) Values by Method
Quarter 3, Specimen 4
Assayed Value (AV)[3] 0.42 µmol/L whole blood



	Quarter 4
Specimen 1	
Enriched	0
CDC Assayed	0.6
Reported Mean	0.7
Specimen 2	
Enriched	0
CDC Assayed	0.5
Reported Mean	0.5
Specimen 3	
Enriched	0
CDC Assayed	0.7
Reported Mean	0.6
Specimen 4	
Enriched	0
CDC Assayed	0.5
Reported Mean	0.4
Specimen 5	
Enriched	3.0
CDC Assayed	2.7
Reported Mean	2.7
CDC Bias[2]	-0.8

Figure 22. Bias Plot of Citrulline Values by Method
Quarter 4, Specimen 5
Expected Value (EV)[1] 3.5 mg/dL whole blood



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]EV minus Assayed (reported) value ± Bias.
[3]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

value for the analyte. In general, the quantitative comparisons (Figures 11-22) for PT challenges are reasonable within a method but vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences. The scatter of values for T_4 (Figure 11) was large and fairly consistent among methods. The TSH and 17-OHP results (Figures 12 and 13) performed consistently among the different methods, with several methods showing some higher values for TSH and 17-OHP. The "other" method group showed the greatest scatter of values among users for both analytes. For the predominately used TSH and 17-OHP methods, the values were consistent, and most had a small positive bias. Comparisons of values for most methods for Gal showed higher values than the expected value, except for one Gal method that gave values close to the expected (assayed) value (Figure 14). For Phe (Figure 15), the reported results showed high variability within and among methods. One Phe method showed low variability among users and close agreement to the expected value but with a predominately negative bias with the expected value. The values reported for Leu (Figure 16) showed reasonable variability with two methods contributing most of the high variability. One Leu method showed close agreement to the expected value and low variability among most users. One method for Met (Figure 17) produced higher values than the others, and another method showed close agreement to the expected value. The most commonly used Met method showed a uniform variance around the expected value. For IRT (Figure 18), the reported results agreed reasonably with the CDC assayed value for most methods, whereas one method gave a very high bias and the "other" group showed a large negative bias.

TABLE 3. 2004 Summary of Proficiency Testing Errors by Domestic and Foreign Laboratories

Domestic	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Hypothyroidism	341	0	585	0.5
Phenylketonuria	214	0	625	0.3
Galactosemia	130	1.5	390	0
Congential Adrenal Hyperplasia	206	0.5	469	0.9
Maple Syrup Urine Disease	126	3.2	213	0.5
Homocystinuria	88	0	262	0
Biotinidase Deficiency	137	0	328	0
GALT Deficiency	184	0.5	736	0.7
Cystic Fibrosis (IRT) - Pilot Phase	88	1.1	56	0
Foreign	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Hypothyroidism	804	0.9	1433	1.4
Phenylketonuria	380	1.6	1144	2.4
Galactosemia	215	0.9	645	0.2
Congential Adrenal Hyperplasia	336	1.5	768	0.1
Maple Syrup Urine Disease	187	5.9	318	1.6
Homocystinuria	114	0	336	2.7
Biotinidase Deficiency	165	0.6	390	0.5
GALT Deficiency	79	5.1	316	3.8
Cystic Fibrosis (IRT) - Pilot Phase	314	1.3	201	0.5

Most Common Reasons for False-Negative Errors Reported by Laboratories

Low quantitative value
Transcription error
Analytic testing error

Bias plots are not shown for all acylcarnitines in the PT challenges; representative plots were chosen. Reported values for C8 (Figure 19) and C10 (Figure 20) closely agreed with the expected values and showed reasonably consistent scatter, especially for C8. The reported values for C5DC by one method were very consistently scattered among laboratories with a low-negative bias with the expected value (Figure 21); however, one method showed a high scatter of values with a large positive bias for some laboratories. Reported values for Cit (Figure 22) showed a large negative bias for most participants but illustrates that one method has a smaller bias with a closer agreement with the expected value.

TABLE 4. 2004 MS/MS Summary of Proficiency Testing Errors by Domestic and Foreign Laboratories

Domestic	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylalanine Screen	166	0	314	0
Leucine Screen	209	0	256	0
Methionine Screen	137	0	317	0.3
Tyrosine Screen	105	2.9	314	0.6
Valine Screen	90	0	275	0.4
Citrulline Screen	102	0	308	0.6
C3 Screen	103	1.0	307	0.3
C4 Screen	82	1.2	328	0.3
C5 Screen	162	1.2	243	0
C5DC Screen	75	0	280	0
C6 Screen	127	0	273	0.7
C8 Screen	151	0.7	349	0
C10 Screen	125	4.0	290	0
C14 Screen	72	1.4	288	0.3
C16 Screen	41	2.4	328	0.6
Foreign	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylalanine Screen	371	1.6	659	1.7
Leucine Screen	399	3.0	476	0.6
Methionine Screen	262	0.4	557	0.7
Tyrosine Screen	246	1.2	729	1.1
Valine Screen	198	2.0	606	0.7
Citrulline Screen	200	0.5	590	0.8
C3 Screen	223	0	697	2.2
C4 Screen	180	1.1	720	1.7
C5 Screen	366	1.6	549	0.9
C5DC Screen	175	1.7	651	0.8
C6 Screen	259	1.5	616	0.5
C8 Screen	295	1.0	693	1.6
C10 Screen	274	1.8	621	0.6
C14 Screen	175	2.9	700	0.1
C16 Screen	97	1.0	740	1.4

Figure 24 shows reproducibility by different methods for 17-OHP for the same specimen analyzed 6 months apart. The most popular method among the users gave very consistent results across both challenges, with a small difference between the two reported results. Some participants reported markedly different values for the two specimens at the two time-points.

Tables 3 and 4 show the proficiency testing errors reported by disorder in 2004 for all qualitative assessments by domestic laboratories and by foreign laboratories. We applied the laboratory-reported specific cutoff values to our grading algorithm for clinical assessments (Figure 23). Presumptive clinical classifications (qualitative assessments) of some specimens may differ by participant because of specific clinical assessment practices. If participants provided us with their cutoff values, we applied these cutoffs in our final appraisal of the error judgment. We based the rates for false-positive misclassifications on the number of distributed negative specimens and the rates for false-negative misclassifications on the number of positive specimens. False-positive misclassifications, which are a cost-benefit issue and a credibility factor for follow-up programs, should be monitored and kept as low as possible. Many of the misclassifications were in the false-positive category, with false-positive rates ranging from 0% to 3.8%. For domestic laboratories, the rate was 0.6% or lower for 18 of 21 biomarkers or disorders; and for foreign laboratories, the rate was 1.6% or greater for seven of 21 biomarkers or disorders. Screening programs are designed to avoid false-negative reports; this precautionary design, however, contributes to false-positive reports and may cause many of the false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 5.9%. False-negative classifications were reported for all biomarkers or disorders, with the highest rate reported for maple syrup urine disease. For 10 biomarkers or disorders, no false-negative errors were reported for the domestic laboratories. A few of our PT specimens fell close to the decision level for classifications and thus rigorously tested the ability of laboratories to make the expected cutoff decision. Most specimens near the mean cutoff value are distributed as not-evaluated specimens and are not included in Tables 3 and 4. Participants' data for these specimens are used to examine the relative analytical performance of the assays.

FIGURE 23. EXPLANATION OF NSQAP GRADING ALGORITHM

Part 1.
The expected clinical assessment (EA) for a proficiency testing (PT) specimen is determined by comparing the expected value (EV), which is the sum of endogenous and enrichment values, with the CDC cutoff. The production of a PT specimen is designed so that the 99% confidence interval (CI) for the expected value (EV) of a positive specimen falls above the CDC cutoff, and the 99% CI for the expected value (EV) of a negative specimen falls below the CDC cutoff. Specimens that do not meet this 99% CI criterion are declared not-gradable/not-evaluated (NE).

Part 2.
When your reported clinical assessment (RA) differs from the expected clinical assessment (EA), the expected value (EV) is compared with the cutoff that you provide. This determines what your laboratory expected clinical assessment (LA) should be. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are the same, but different from your reported clinical assessment (RA), your grade is either false-negative or false-positive. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are not the same, your reported clinical assessment (RA) will not be graded as incorrect because of a significant difference between the CDC cutoff and your cutoff (see examples below). If you do not provide a cutoff, your laboratory expected clinical assessment (LA) cannot be determined; and your grade will be based on the CDC cutoff.

Part 3.
NSQAP's determination of a final clinical assessment for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations (http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.929), whereby the PT provider "must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories." A NSQAP gradable specimen must have 80% or more agreement among domestic laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated (NE).

Examples of Grading Scenarios

Analyte	CDC Cutoff	Expected Value (EV)	Lab Cutoff	Assessment: (EA) EV/CDC cutoff	Assessment: (LA) EV/Lab cutoff	Assessment: (RA) Lab reported	Lab Grade
TSH	25	13	30	Neg	Neg	Pos	FP
TSH	25	13	10	Neg	Pos	Pos	CD
Leu	4.1	6.7	4.5	Pos	Pos	Neg	FN
Leu	4.1	6.7	8.0	Pos	Neg	Neg	CD

FN = False negative
FP = False positive
CD = Cutoff Difference - clinical assessment is not judged as incorrect

TSH = Thyroid-stimulating Hormone
Leu = Leucine

Note that the grade is based on the reported clinical assessment, not on the reported value. Overall Statistics, which are generated from all participants' data, and Mean Reported Concentrations by method are provided on this Web site for analytical reference only.

FIGURE 24. Reproducibility of Participants' Results by Different Methods - 17 α-Hydroxyprogesterone

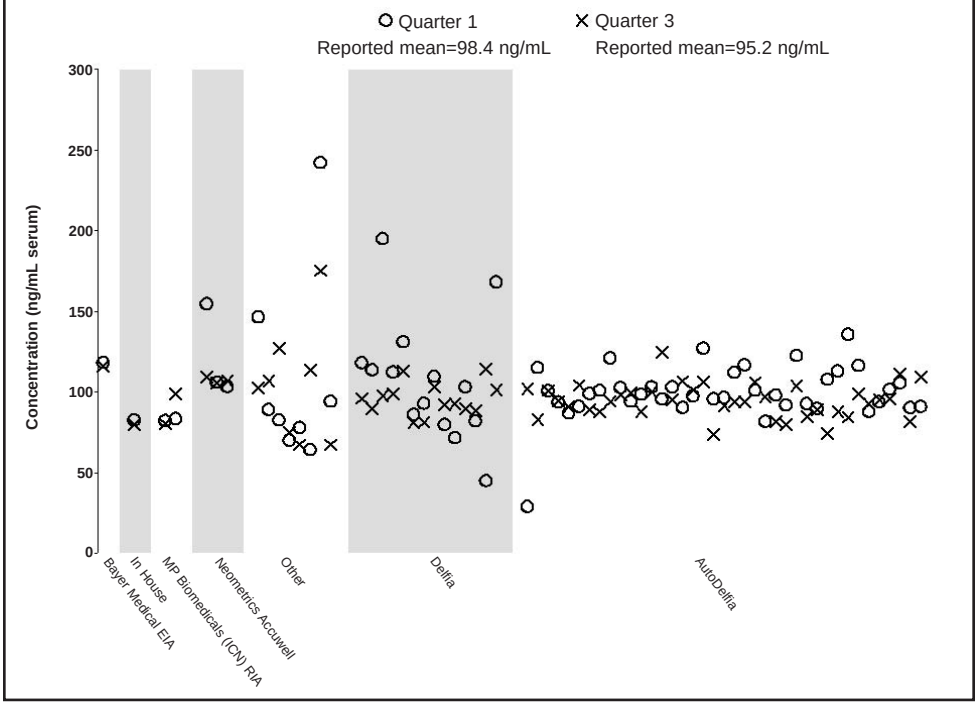


Table 5 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.9% to 4.9% for the error categories, with 49 of 72 laboratories correctly classifying all specimens. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 6 shows the phenotype challenges that were distributed in 2004 for hemoglobinopathies.

Table 7 shows the CF genotype challenges in 2004, which were combined with varying levels of IRT to yield a total challenge of the test algorithm for presumptive positive classifications.

Low quantitative values were the most frequent explanation among the most common reasons for false-negative errors reported by domestic participants identified upon follow-up by NSQAP.

QUALITY CONTROL

For QC shipments of T_4, TSH, 17-OHP, Gal, amino acids (Phe, Leu, Met, Tyr, Val, Cit), and acylcarnitines (C2, C3, C4, C5, C5DC, C6, C8, C10, C14, C16), each lot within a set contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used a randomizing system to select the set of sheets from the production batch for each laboratory. The QC materials were distributed semiannually and included the DBS sheets, instructions for storage and analysis, and data-report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear and annual summary reports distributed to each participant. Intervals between runs were not the same for all laboratories because each participant's reported data cover a different time span.

The reported QC data are summarized in Tables 9a-9t, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the within laboratory and total standard deviations (SD) by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Linear regressions (Y-intercept and slope) were calculated by method for all analytic values within an analyte QC series. Values outside the 99% CI (outliers) were excluded from the calculations.

Tables 9a-9t provide data about method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from one batch of hematocrit-adjusted, nonenriched blood, the endogenous concentration was the same for all specimens in a lot series. We calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We calculated the Y-intercept and slope in each table using all analyte con-

TABLE 5. Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	960	185
Phenotype errors	1.1%	4.3%
Clinical assessment errors	0.9%	4.9%

Overall, 19 phenotype errors occurred in 2004: one SS, one FAS, two FS + Barts, eight FAD, and seven different versions of FAD.

TABLE 6. Hemoglobin Phenotype Challenges Distributed in 2004

Phenotype	N
FA	5
FS	3
FE	1
FAC	4
FAS	5
FAG	1
FSC	1

centrations within a lot series (e.g., lots 311, 312, and 313). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For Phe, Leu, Met, Tyr, Val, and Cit, participants also measured the endogenous concentrations by analyzing the nonenriched QC lots; the Y-intercepts and measured endogenous levels for these analytes were similar for most methods. Ideally, the slope should be 1.0, and most slopes were close to this value; however, the range was 0.58 to 2.12 because of a few methods and analytes. Three TSH methods had slopes higher than expected, with values of 1.3, 1.4 and 1.6 (lots 311-313 and 411-413), and one method showed a low value of 0.7 (lots 311-313). Four Gal methods yielded slopes of 1.3, 1.4, 1.5, and 1.8 (lots 321-324); and for two Gal methods, slopes of 1.3 and 1.5 (lots 325-328) and 1.3 and 1.4 (lots 421-424). Four Phe methods had slopes of 1.3 to 1.4 for lots 321-324, one Phe method had a slope of 1.3 for lots 325-328, and all slopes for lots 421-424 were within the expected range for the Phe methods. One Leu method and one Met method had slopes of 1.5 and 1.3 (lots 321-324), respectively. Two Val methods had a low slope value of 0.7 (lots 325-328). One Cit method had a low slope value of 0.7 (lots 421-424). Similar to the midyear report (slope 0.71), the same C2 method for the same QC lots (lots 365-368) had a slope of 0.63 apparently caused by low values on the two higher value pools (lots 367-368), and both methods had slopes of 0.76 and 0.58 for the newer QC lots (461-464). The base serum pool (zero enrichment) for lots 365 and 461 had higher values before enrichment than the previous lot 361 for C2. This higher base pool value may contribute to the low slope values. For C5DC measured by the kit method, the slopes were 1.49 and 2.12 (lots 461-464 and 365-368, respectively), and for the non-kit method the slope was 0.74 (lots 461-464). Numerous different internal standards were used to calculatate C5DC values by both kit and non-kit methods. Laboratories in each group indicated using derivatized and non-derivatized methods. The data were not sorted by type of internal standard or by derivatized and non-derivatized methods. These differences could contribute to the large "total SDs" and other variances shown in Table 9o.

Slope deviations may be related to analytic (dose-response) ranges for calibration curves or to poor recoveries for one or more specimens in a three- or four-specimen QC set. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate a method has an analytic bias.

REFERENCES

1. Hannon WH, Baily CM, Bartoshesky LE, Davin B, Hoffman GL, King PP, et al. Blood collection on filter paper for newborn screening programs. Fourth edition, approved standard. Wayne (PA): NCCLS; 2003 NCCLS Document LA4-A4.

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TABLE 7. Genotype Analysis of IRT Positive Cystic Fibrosis Specimens in 2004

Genotype	Number of Results	Correct Results (%)
Δ508/Δ508	93	83 (89.2%)
Δ508/Wild Type	21	19 (90.5%)
Wild Type/Wild Type	36	36 (100%)

Methods Used: Orchid Biosciences Elucigene (ARMS); Roche Linear Array (ASO); Innogenetics Auto-LiPA; In-house PCR.

TABLE 9a. 2004 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (µg T_4/dL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 201 - Enriched 2 µg/dL serum						
Diagnostic Products	20	2.3	0.4	0.4	0.4	0.9
MP Biomedicals (ICN) RIA	70	2.1	0.3	0.4	0.0	1.0
Neometrics Accuwell	97	2.2	0.4	0.5	-0.1	1.1
Delfia	220	1.8	0.6	0.8	-0.3	1.0
AutoDelfia	480	1.7	0.5	0.6	-0.2	0.9
Other	69	1.9	0.3	0.5	-0.3	1.1
Lot 202 - Enriched 5.5 µg/dL serum						
Diagnostic Products	19	5.1	0.8	0.8	0.4	0.9
MP Biomedicals (ICN) RIA	99	5.4	0.7	0.8	0.0	1.0
Neometrics Accuwell	95	6.0	0.8	1.0	-0.1	1.1
Delfia	218	5.0	1.5	2.0	-0.3	1.0
AutoDelfia	482	5.1	0.8	1.5	-0.2	0.9
Other	70	5.7	0.7	0.8	-0.3	1.1
Lot 203 - Enriched 8 µg/dL serum						
Diagnostic Products	20	7.7	1.1	1.1	0.4	0.9
MP Biomedicals (ICN) RIA	96	8.0	0.9	1.1	0.0	1.0
Neometrics Accuwell	95	9.1	1.1	1.6	-0.1	1.1
Delfia	219	7.8	1.9	2.7	-0.3	1.0
AutoDelfia	475	7.3	0.9	2.3	-0.2	0.9
Other	68	8.5	1.0	1.0	-0.3	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROXINE (µg T_4/dL serum)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 301 - Enriched 2 µg/dL serum						
Diagnostic Products	10	2.1	0.2	0.2	0.3	1.0
MP Biomedicals (ICN) RIA	30	1.7	0.2	0.6	0.0	0.9
Neometrics Accuwell	49	1.9	0.4	0.5	-0.1	1.1
Delfia	136	1.5	0.7	0.9	-0.3	0.9
AutoDelfia	223	1.4	0.4	0.6	-0.4	0.9
Other	40	1.8	0.3	0.6	-0.2	1.0
Lot 302 - Enriched 7 µg/dL serum						
Diagnostic Products	10	7.4	0.8	0.8	0.3	1.0
MP Biomedicals (ICN) RIA	50	6.0	0.6	0.9	0.0	0.9
Neometrics Accuwell	50	7.5	1.0	1.3	-0.1	1.1
Delfia	132	6.2	1.1	2.5	-0.3	0.9
AutoDelfia	233	6.1	0.7	1.4	-0.4	0.9
Other	39	6.9	0.7	0.7	-0.2	1.0
Lot 303 - Enriched 11 µg/dL serum						
Diagnostic Products	10	10.8	0.7	0.7	0.3	1.0
MP Biomedicals (ICN) RIA	50	9.4	1.6	2.5	0.0	0.9
Neometrics Accuwell	50	11.5	1.3	1.7	-0.1	1.1
Delfia	131	10.0	1.3	4.0	-0.3	0.9
AutoDelfia	228	9.5	1.1	2.3	-0.4	0.9
Other	40	11.1	0.8	1.2	-0.2	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9b. 2004 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (µIU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 311 - Enriched 25 µIU/mL serum						
Diagnostic Products	69	30.8	3.5	3.7	2.0	1.1
Neometrics Accuwell	98	23.2	3.0	3.9	-2.7	1.0
MP Biomedicals (ICN) IRMA	120	35.3	3.4	10.8	6.5	1.2
MP Biomedicals (ICN) ELISA	49	24.5	5.4	7.4	-1.6	1.0
Delfia	876	26.4	3.3	4.6	0.6	1.0
AutoDelfia	1152	25.7	2.7	4.0	-0.1	1.0
Ani Labsystems (Thermo)	40	25.9	1.7	4.9	5.1	0.9
Bio-Rad Quantase	254	26.2	4.0	5.2	-3.6	1.2
TecnoSuma UMELISA	29	26.4	5.2	5.2	-9.0	1.3
Bioclone ELISA	19	29.2	3.8	3.8	7.4	0.7
In house	140	27.1	3.8	4.7	2.3	1.0
Other	545	28.0	4.7	8.1	1.7	1.0
Lot 312 - Enriched 40 µIU/mL serum						
Diagnostic Products	68	46.4	4.2	4.3	2.0	1.1
Neometrics Accuwell	99	38.3	6.5	8.8	-2.7	1.0
MP Biomedicals (ICN) IRMA	120	52.4	4.7	16.8	6.5	1.2
MP Biomedicals (ICN) ELISA	50	37.5	2.8	6.8	-1.6	1.0
Delfia	873	42.2	5.4	7.9	0.6	1.0
AutoDelfia	1155	40.3	4.2	6.3	-0.1	1.0
Ani Labsystems (Thermo)	40	40.5	3.3	7.2	5.1	0.9
Bio-Rad Quantase	248	43.7	7.1	8.3	-3.6	1.2
TecnoSuma UMELISA	30	36.7	8.6	8.6	-9.0	1.3
Bioclone ELISA	20	33.5	6.8	6.8	7.4	0.7
In house	138	42.6	6.1	9.8	2.3	1.0
Other	545	41.8	7.5	12.2	1.7	1.0
Lot 313 - Enriched 80 µIU/mL serum						
Diagnostic Products	69	92.6	8.0	8.0	2.0	1.1
Neometrics Accuwell	100	79.8	10.3	17.2	-2.7	1.0
MP Biomedicals (ICN) IRMA	120	98.6	10.2	28.2	6.5	1.2
MP Biomedicals (ICN) ELISA	49	79.4	9.1	25.1	-1.6	1.0
Delfia	876	83.5	9.2	13.4	0.6	1.0
AutoDelfia	1153	81.6	7.7	12.0	-0.1	1.0
Ani Labsystems (Thermo)	40	73.6	6.5	10.7	5.1	0.9
Bio-Rad Quantase	248	91.4	14.8	17.9	-3.6	1.2
TecnoSuma UMELISA	30	93.6	15.7	16.5	-9.0	1.3
Bioclone ELISA	18	68.6	14.0	14.0	7.4	0.7
In house	137	82.3	13.6	19.5	2.3	1.0
Other	542	84.1	11.8	21.5	1.7	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROID-STIMULATING HORMONE (µIU/mL serum)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 411 - Enriched 25 µIU/mL serum						
Diagnostic Products	39	30.8	2.7	3.0	0.0	1.2
Neometrics Accuwell	49	28.2	4.3	5.7	-0.3	1.1
MP Biomedicals (ICN) IRMA	40	44.4	6.7	12.3	9.2	1.4
MP Biomedicals (ICN) ELISA	28	24.2	3.2	3.3	-2.6	1.0
Delfia	428	27.5	3.3	5.1	-1.3	1.1
AutoDelfia	628	26.9	2.6	3.8	-2.2	1.2
Ani Labsystems (Thermo)	20	30.4	1.3	3.5	3.1	1.1
Bio-Rad Quantase	149	27.9	6.9	11.1	-1.8	1.2
TecnoSuma UMELISA	20	28.4	4.5	4.5	12.7	0.8
Bioclone ELISA	20	40.6	4.4	16.9	-1.5	1.6
In house	89	27.6	4.3	5.4	-0.2	1.1
Other	222	25.9	3.2	9.0	-0.1	1.1
Lot 412 - Enriched 40 µIU/mL serum						
Diagnostic Products	40	49.8	3.6	4.1	0.0	1.2
Neometrics Accuwell	50	43.8	5.0	6.5	-0.3	1.1
MP Biomedicals (ICN) IRMA	40	62.1	7.3	16.1	9.2	1.4
MP Biomedicals (ICN) ELISA	30	37.0	3.5	4.6	-2.6	1.0
Delfia	434	44.3	6.2	8.6	-1.3	1.1
AutoDelfia	625	43.9	4.0	6.1	-2.2	1.2
Ani Labsystems (Thermo)	20	44.8	2.0	5.5	3.1	1.1
Bio-Rad Quantase	138	46.3	6.8	14.3	-1.8	1.2
TecnoSuma UMELISA	20	50.3	4.3	13.6	12.7	0.8
Bioclone ELISA	20	62.5	9.1	18.3	-1.5	1.6
In house	88	46.3	6.1	8.2	-0.2	1.1
Other	228	43.9	5.6	12.6	-0.1	1.1
Lot 413 - Enriched 80 µIU/mL serum						
Diagnostic Products	40	99.0	5.0	6.0	0.0	1.2
Neometrics Accuwell	48	89.5	7.4	11.2	-0.3	1.1
MP Biomedicals (ICN) IRMA	40	118.5	12.4	30.4	9.2	1.4
MP Biomedicals (ICN) ELISA	30	79.9	7.0	7.0	-2.6	1.0
Delfia	424	90.5	11.4	16.3	-1.3	1.1
AutoDelfia	609	90.6	8.3	12.9	-2.2	1.2
Ani Labsystems (Thermo)	20	88.7	1.7	2.0	3.1	1.1
Bio-Rad Quantase	150	93.8	15.5	29.7	-1.8	1.2
TecnoSuma UMELISA	19	74.7	10.8	13.3	12.7	0.8
Bioclone ELISA	19	130.1	13.2	55.0	-1.5	1.6
In house	89	90.6	11.5	15.5	-0.2	1.1
Other	221	85.4	9.1	24.3	-0.1	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9c. 2004 Quality Control Data
Summaries of Statistical Analyses

17 α-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 351 - Enriched 25 ng/mL serum						
MP Biomedicals (ICN) RIA	50	26.0	4.5	5.8	4.2	0.9
Neometrics Accuwell	60	29.6	3.6	3.6	2.0	1.1
Delfia	237	26.7	3.2	4.5	-2.8	1.1
AutoDelfia	729	28.0	3.0	4.4	-1.7	1.1
Bayer Medical EIA	30	29.0	3.1	4.5	-1.9	1.2
In house	49	21.8	6.0	7.2	1.7	0.8
Other	117	29.0	4.7	6.7	1.5	1.1
Lot 352 - Enriched 50 ng/mL serum						
MP Biomedicals (ICN) RIA	49	47.7	4.9	5.7	4.2	0.9
Neometrics Accuwell	58	57.2	7.1	7.1	2.0	1.1
Delfia	246	51.2	7.4	9.8	-2.8	1.1
AutoDelfia	728	53.1	6.3	8.8	-1.7	1.1
Bayer Medical EIA	30	55.0	5.6	6.4	-1.9	1.2
In house	49	41.2	6.5	7.1	1.7	0.8
Other	119	53.4	7.3	10.4	1.5	1.1
Lot 353 - Enriched 100 ng/mL serum						
MP Biomedicals (ICN) RIA	49	91.2	9.4	11.9	4.2	0.9
Neometrics Accuwell	59	112.2	19.0	19.0	2.0	1.1
Delfia	242	110.0	14.9	21.2	-2.8	1.1
AutoDelfia	727	112.6	12.9	18.0	-1.7	1.1
Bayer Medical EIA	29	117.0	10.3	10.3	-1.9	1.2
In house	47	81.5	15.6	16.5	1.7	0.8
Other	116	108.4	14.9	25.1	1.5	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9d. 2004 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	149	5.9	1.0	1.9	0.9	1.0
Fluor Cont Flow, Kit	80	7.5	0.6	1.1	2.1	1.1
Colorimetric	52	7.2	1.3	1.5	1.2	1.3
PerkinElmer Neonatal Fluor	128	8.4	1.0	1.5	4.0	0.8
Neometrics Accuwell	30	7.8	0.8	1.9	0.6	1.5
Bio-Rad Quantase	70	7.3	1.1	1.8	-1.2	1.8
Interscientific Enzyme	40	5.6	0.7	1.5	-1.3	1.3
Other	59	6.3	1.4	2.5	0.2	1.2
Lot 322 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	147	11.1	1.4	2.5	0.9	1.0
Fluor Cont Flow, Kit	78	13.3	1.3	1.7	2.1	1.1
Colorimetric	50	14.1	1.6	2.3	1.2	1.3
PerkinElmer Neonatal Fluor	128	11.6	1.1	1.4	4.0	0.8
Neometrics Accuwell	30	15.4	1.3	4.0	0.6	1.5
Bio-Rad Quantase	70	16.9	1.8	2.8	-1.2	1.8
Interscientific Enzyme	38	11.8	1.8	2.8	-1.3	1.3
Other	60	12.2	1.4	2.4	0.2	1.2
Lot 323 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	149	17.3	2.1	3.8	0.9	1.0
Fluor Cont Flow, Kit	79	19.8	1.3	1.9	2.1	1.1
Colorimetric	50	20.7	2.2	3.9	1.2	1.3
PerkinElmer Neonatal Fluor	128	15.9	1.4	1.7	4.0	0.8
Neometrics Accuwell	30	22.3	2.3	5.6	0.6	1.5
Bio-Rad Quantase	69	26.0	2.8	4.3	-1.2	1.8
Interscientific Enzyme	37	18.3	3.0	4.0	-1.3	1.3
Other	60	19.0	1.5	2.4	0.2	1.2
Lot 324 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	144	32.0	3.7	6.0	0.9	1.0
Fluor Cont Flow, Kit	79	35.9	2.6	3.9	2.1	1.1
Colorimetric	50	39.2	3.8	6.5	1.2	1.3
PerkinElmer Neonatal Fluor	128	28.2	2.3	3.1	4.0	0.8
Neometrics Accuwell	30	44.3	6.0	11.1	0.6	1.5
Bio-Rad Quantase	72	52.3	6.4	8.5	-1.2	1.8
Interscientific Enzyme	40	38.5	5.4	9.7	-1.3	1.3
Other	58	37.0	4.2	6.1	0.2	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	246	5.5	0.9	1.9	0.5	1.0
Fluor Cont Flow, Kit	128	7.9	0.7	1.3	2.2	1.1
Colorimetric	117	7.1	1.1	1.8	1.4	1.2
PerkinElmer Neonatal Fluor	312	7.8	1.3	1.9	4.0	0.8
Neometrics Accuwell	58	6.9	1.6	1.8	0.8	1.2
Bio-Rad Quantase	129	6.9	1.2	1.5	-0.6	1.5
Interscientific Enzyme	77	5.5	0.6	1.2	-0.2	1.1
Other	129	6.8	1.4	1.8	0.5	1.3
Lot 326 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	241	10.5	1.4	2.5	0.5	1.0
Fluor Cont Flow, Kit	127	13.1	1.0	1.9	2.2	1.1
Colorimetric	120	13.3	1.6	3.1	1.4	1.2
PerkinElmer Neonatal Fluor	317	12.1	1.4	2.0	4.0	0.8
Neometrics Accuwell	60	13.3	3.1	3.3	0.8	1.2
Bio-Rad Quantase	119	14.9	2.1	2.9	-0.6	1.5
Interscientific Enzyme	78	10.9	1.8	2.9	-0.2	1.1
Other	130	13.4	1.8	2.7	0.5	1.3
Lot 327 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	251	16.2	1.9	3.2	0.5	1.0
Fluor Cont Flow, Kit	126	18.8	1.6	2.6	2.2	1.1
Colorimetric	120	19.3	2.1	4.2	1.4	1.2
PerkinElmer Neonatal Fluor	319	16.3	3.1	3.3	4.0	0.8
Neometrics Accuwell	60	19.4	4.3	4.8	0.8	1.2
Bio-Rad Quantase	128	21.7	3.7	4.9	-0.6	1.5
Interscientific Enzyme	77	17.0	2.4	3.1	-0.2	1.1
Other	130	19.4	2.5	3.5	0.5	1.3
Lot 328 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	240	31.1	3.2	5.6	0.5	1.0
Fluor Cont Flow, Kit	126	35.5	2.7	4.3	2.2	1.1
Colorimetric	120	36.8	4.1	6.5	1.4	1.2
PerkinElmer Neonatal Fluor	316	28.1	3.0	3.4	4.0	0.8
Neometrics Accuwell	60	38.0	8.3	9.3	0.8	1.2
Bio-Rad Quantase	115	44.8	6.5	9.1	-0.6	1.5
Interscientific Enzyme	75	33.7	5.4	8.6	-0.2	1.1
Other	132	38.5	4.3	7.5	0.5	1.3

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	107	5.8	1.4	2.2	0.9	1.0
Fluor Cont Flow, Kit	50	7.8	0.7	1.2	2.3	1.1
Colorimetric	80	7.3	1.0	2.1	1.3	1.2
PerkinElmer Neonatal Fluor	178	8.0	1.2	1.7	4.3	0.8
Neometrics Accuwell	30	6.2	0.5	0.5	0.8	1.1
Bio-Rad Quantase	48	6.3	1.0	1.1	-1.2	1.4
Interscientific Enzyme	39	6.0	0.9	1.1	0.2	1.1
Other	80	7.0	1.4	1.6	0.7	1.3
Lot 422 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	108	10.6	1.3	1.5	0.9	1.0
Fluor Cont Flow, Kit	50	12.8	0.9	1.6	2.3	1.1
Colorimetric	80	13.7	1.4	3.8	1.3	1.2
PerkinElmer Neonatal Fluor	181	11.6	1.5	1.9	4.3	0.8
Neometrics Accuwell	30	11.0	0.7	0.9	0.8	1.1
Bio-Rad Quantase	59	12.0	1.6	2.3	-1.2	1.4
Interscientific Enzyme	39	10.6	1.1	1.8	0.2	1.1
Other	80	13.0	1.6	2.4	0.7	1.3
Lot 423 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	108	15.7	1.7	2.2	0.9	1.0
Fluor Cont Flow, Kit	50	18.1	1.0	2.7	2.3	1.1
Colorimetric	80	19.6	1.7	5.5	1.3	1.2
PerkinElmer Neonatal Fluor	178	17.3	1.6	2.1	4.3	0.8
Neometrics Accuwell	30	17.2	1.2	1.2	0.8	1.1
Bio-Rad Quantase	59	19.3	2.9	5.0	-1.2	1.4
Interscientific Enzyme	40	16.4	1.9	3.3	0.2	1.1
Other	76	20.2	2.8	4.2	0.7	1.3
Lot 424 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	110	30.3	2.8	3.4	0.9	1.0
Fluor Cont Flow, Kit	50	34.4	2.4	4.9	2.3	1.1
Colorimetric	80	38.2	3.2	8.2	1.3	1.2
PerkinElmer Neonatal Fluor	181	27.6	2.6	3.1	4.3	0.8
Neometrics Accuwell	30	32.7	2.5	2.5	0.8	1.1
Bio-Rad Quantase	58	40.1	4.9	7.5	-1.2	1.4
Interscientific Enzyme	39	32.7	3.9	5.8	0.2	1.1
Other	80	38.5	4.2	8.0	0.7	1.3

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9e. 2004 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL whole blood						
Fluorometric Manual	78	1.8	0.3	0.5	1.9	1.0
Bacterial Inhibition (Guthrie)	90	1.6	0.3	0.6	1.4	1.0
Fluor Cont Flo, In house	19	2.2	0.3	0.3	2.0	1.3
Fluor Cont Flo, Kit	138	2.1	0.2	0.5	2.0	1.1
Colorimetric	70	1.8	0.3	0.5	1.8	1.4
PerkinElmer Neonatal Fluor	263	1.5	0.2	0.3	1.5	1.0
HPLC	70	1.4	0.1	0.2	1.5	1.0
MS/MS Non-Kit	374	1.5	0.1	0.3	1.5	1.0
MS/MS PE Neogram MS2 Kit	50	1.5	0.2	0.2	1.4	0.9
Neometrics Accuwell	30	2.0	0.3	0.4	2.0	1.3
Bio-Rad Quantase	90	1.5	0.3	0.3	1.5	1.1
MP Biomed (ICN) Enzyme	12	1.2	0.3	0.3	1.5	1.3
Interscientific Enzyme	49	1.6	0.4	0.6	1.4	1.1
Other	59	2.2	0.5	0.9	2.0	1.1
Lot 322 - Enriched 3 mg/dL whole blood						
Fluorometric Manual	80	5.1	0.5	0.7	1.9	1.0
Bacterial Inhibition (Guthrie)	110	4.1	0.5	1.1	1.4	1.0
Fluor Cont Flo, In house	19	5.7	0.4	0.5	2.0	1.3
Fluor Cont Flo, Kit	138	5.4	0.5	1.0	2.0	1.1
Colorimetric	69	5.9	0.9	1.4	1.8	1.4
PerkinElmer Neonatal Fluor	265	4.3	0.4	0.5	1.5	1.0
HPLC	79	4.4	0.3	0.4	1.5	1.0
MS/MS Non-Kit	374	4.5	0.4	0.7	1.5	1.0
MS/MS PE Neogram MS2 Kit	47	4.1	0.5	0.5	1.4	0.9
Neometrics Accuwell	29	5.8	0.5	1.0	2.0	1.3
Bio-Rad Quantase	85	4.7	0.5	0.7	1.5	1.1
MP Biomed (ICN) Enzyme	20	5.3	0.9	0.9	1.5	1.3
Interscientific Enzyme	57	4.5	0.7	1.2	1.4	1.1
Other	59	5.1	0.7	1.4	2.0	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 323 - Enriched 7 mg/dL whole blood						
Fluorometric Manual	78	9.2	0.7	0.9	1.9	1.0
Bacterial Inhibition (Guthrie)	109	8.3	1.1	1.5	1.4	1.0
Fluor Cont Flo, In house	20	11.1	0.8	0.8	2.0	1.3
Fluor Cont Flo, Kit	135	9.9	1.2	2.2	2.0	1.1
Colorimetric	69	11.5	0.9	2.6	1.8	1.4
PerkinElmer Neonatal Fluor	266	8.4	0.8	0.9	1.5	1.0
HPLC	69	9.0	1.3	1.4	1.5	1.0
MS/MS Non-Kit	371	8.7	0.8	1.4	1.5	1.0
MS/MS PE Neogram MS2 Kit	49	8.3	1.0	1.0	1.4	0.9
Neometrics Accuwell	30	11.2	0.6	2.0	2.0	1.3
Bio-Rad Quantase	90	9.5	1.0	1.3	1.5	1.1
MP Biomed (ICN) Enzyme	20	10.9	0.9	1.1	1.5	1.3
Interscientific Enzyme	57	8.9	0.9	1.9	1.4	1.1
Other	58	9.7	1.1	2.6	2.0	1.1
Lot 324 - Nonenriched 11 mg/dL whole blood						
Fluorometric Manual	78	13.1	1.1	1.3	1.9	1.0
Bacterial Inhibition (Guthrie)	107	12.2	2.0	2.5	1.4	1.0
Fluor Cont Flo, In house	20	16.4	0.9	0.9	2.0	1.3
Fluor Cont Flo, Kit	138	14.6	1.1	2.7	2.0	1.1
Colorimetric	72	17.1	0.9	3.5	1.8	1.4
PerkinElmer Neonatal Fluor	257	12.5	1.1	1.2	1.5	1.0
HPLC	80	12.5	0.7	1.2	1.5	1.0
MS/MS Non-Kit	374	12.7	1.3	2.2	1.5	1.0
MS/MS PE Neogram MS2 Kit	50	11.8	1.2	1.3	1.4	0.9
Neometrics Accuwell	30	16.2	1.1	2.9	2.0	1.3
Bio-Rad Quantase	88	13.6	1.1	1.7	1.5	1.1
MP Biomed (ICN) Enzyme	20	15.2	1.6	1.6	1.5	1.3
Interscientific Enzyme	59	13.7	1.2	3.1	1.4	1.1
Other	64	14.0	1.6	3.0	2.0	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 - Enriched 0 mg/dL whole blood						
Fluorometric Manual	157	1.7	0.3	0.4	1.7	1.1
Bacterial Inhibition (Guthrie)	154	1.8	0.4	0.5	1.8	1.0
Fluor Cont Flo, In house	56	2.1	0.2	0.3	2.0	1.2
Fluor Cont Flo, Kit	262	2.1	0.4	0.7	2.0	1.1
Colorimetric	186	1.9	0.4	0.5	1.8	1.3
PerkinElmer Neonatal Fluor	607	1.5	0.3	0.3	1.5	1.0
HPLC	128	1.5	0.2	0.2	1.4	1.0
MS/MS Non-Kit	851	1.5	0.2	0.3	1.5	1.0
MS/MS PE Neogram MS2 Kit	176	1.5	0.2	0.2	1.5	1.0
Neometrics Accuwell	69	1.9	0.3	0.4	1.8	1.2
Bio-Rad Quantase	225	1.5	0.4	0.5	1.4	1.1
MP Biomed (ICN) Enzyme	28	1.5	0.5	0.6	1.3	1.2
Interscientific Enzyme	103	1.6	0.4	0.5	1.5	1.1
Other	80	2.3	0.4	0.7	2.2	1.1
Lot 326 - Nonenriched 3 mg/dL whole blood						
Fluorometric Manual	157	5.0	0.5	0.7	1.7	1.1
Bacterial Inhibition (Guthrie)	200	4.7	0.7	1.0	1.8	1.0
Fluor Cont Flo, In house	56	5.7	0.4	0.9	2.0	1.2
Fluor Cont Flo, Kit	262	5.4	0.6	1.3	2.0	1.1
Colorimetric	188	5.7	0.6	1.2	1.8	1.3
PerkinElmer Neonatal Fluor	610	4.5	0.5	1.9	1.5	1.0
HPLC	150	4.4	0.3	0.4	1.4	1.0
MS/MS Non-Kit	861	4.6	0.5	0.8	1.5	1.0
MS/MS PE Neogram MS2 Kit	177	4.5	0.5	0.7	1.5	1.0
Neometrics Accuwell	70	5.5	0.5	0.6	1.8	1.2
Bio-Rad Quantase	228	4.7	0.6	0.8	1.4	1.1
MP Biomed (ICN) Enzyme	40	4.9	0.7	0.8	1.3	1.2
Interscientific Enzyme	109	4.9	0.8	1.2	1.5	1.1
Other	79	5.4	0.6	0.9	2.2	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 327 - Enriched 7 mg/dL whole blood						
Fluorometric Manual	157	9.2	0.8	1.0	1.7	1.1
Bacterial Inhibition (Guthrie)	198	8.5	1.0	1.4	1.8	1.0
Fluor Cont Flo, In house	56	10.5	0.9	1.6	2.0	1.2
Fluor Cont Flo, Kit	261	9.8	1.0	2.2	2.0	1.1
Colorimetric	187	10.5	1.0	2.2	1.8	1.3
PerkinElmer Neonatal Fluor	612	8.4	0.9	1.3	1.5	1.0
HPLC	129	8.8	0.7	0.8	1.4	1.0
MS/MS Non-Kit	857	8.6	0.9	1.3	1.5	1.0
MS/MS PE Neogram MS2 Kit	175	8.2	0.9	1.3	1.5	1.0
Neometrics Accuwell	70	10.2	1.1	1.3	1.8	1.2
Bio-Rad Quantase	227	9.0	1.1	1.3	1.4	1.1
MP Biomed (ICN) Enzyme	40	9.6	1.1	1.5	1.3	1.2
Interscientific Enzyme	104	9.1	0.9	2.0	1.5	1.1
Other	89	9.7	1.3	1.9	2.2	1.1
Lot 328 - Nonenriched 11 mg/dL whole blood						
Fluorometric Manual	160	13.5	1.3	1.4	1.7	1.1
Bacterial Inhibition (Guthrie)	193	12.7	1.7	2.4	1.8	1.0
Fluor Cont Flo, In house	56	15.8	1.4	3.0	2.0	1.2
Fluor Cont Flo, Kit	266	14.7	2.1	3.5	2.0	1.1
Colorimetric	184	16.1	1.8	3.3	1.8	1.3
PerkinElmer Neonatal Fluor	601	12.7	1.3	1.9	1.5	1.0
HPLC	148	12.7	0.9	1.3	1.4	1.0
MS/MS Non-Kit	867	12.9	1.2	1.9	1.5	1.0
MS/MS PE Neogram MS2 Kit	180	12.1	1.3	1.8	1.5	1.0
Neometrics Accuwell	70	15.3	1.9	2.1	1.8	1.2
Bio-Rad Quantase	219	13.7	1.3	1.6	1.4	1.1
MP Biomed (ICN) Enzyme	40	14.7	1.5	2.2	1.3	1.2
Interscientific Enzyme	108	14.1	1.6	2.8	1.5	1.1
Other	86	14.3	1.5	2.4	2.2	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Enriched 0 mg/dL whole blood						
Fluorometric Manual	80	1.8	0.2	0.3	2.0	0.9
Bacterial Inhibition (Guthrie)	70	1.7	0.3	0.4	1.8	0.9
Fluor Cont Flo, In house	16	2.3	0.2	0.3	2.4	1.2
Fluor Cont Flo, Kit	99	2.1	0.4	0.7	2.1	1.1
Colorimetric	107	1.7	0.3	0.4	1.8	1.1
PerkinElmer Neonatal Fluor	264	1.4	0.7	0.8	1.5	0.9
HPLC	60	1.4	0.1	0.2	1.5	0.9
MS/MS Non-Kit	494	1.5	0.2	0.3	1.5	0.9
MS/MS PE Neogram MS2 Kit	148	1.5	0.1	0.2	1.7	0.9
Neometrics Accuwell	39	1.7	0.3	0.3	1.5	1.1
Bio-Rad Quantase	126	1.4	0.3	0.4	1.2	1.0
MP Biomed (ICN) Enzyme	20	1.2	0.4	0.5	1.6	1.0
Interscientific Enzyme	50	1.4	0.2	0.2	1.5	1.0
Other	30	2.7	0.6	0.7	2.5	1.0
Lot 422 - Nonenriched 3 mg/dL whole blood						
Fluorometric Manual	80	5.0	0.5	0.6	2.0	0.9
Bacterial Inhibition (Guthrie)	82	4.6	0.4	0.6	1.8	0.9
Fluor Cont Flo, In house	16	6.1	0.7	0.7	2.4	1.2
Fluor Cont Flo, Kit	97	5.4	0.5	1.1	2.1	1.1
Colorimetric	108	5.3	0.5	1.2	1.8	1.1
PerkinElmer Neonatal Fluor	255	4.2	0.4	0.7	1.5	0.9
HPLC	68	4.3	0.3	0.5	1.5	0.9
MS/MS Non-Kit	492	4.4	0.5	0.8	1.5	0.9
MS/MS PE Neogram MS2 Kit	149	4.4	0.4	0.7	1.7	0.9
Neometrics Accuwell	40	4.5	0.4	0.6	1.5	1.1
Bio-Rad Quantase	126	4.0	0.5	0.9	1.2	1.0
MP Biomed (ICN) Enzyme	20	4.9	0.5	1.3	1.6	1.0
Interscientific Enzyme	50	4.3	0.4	0.4	1.5	1.0
Other	30	5.3	0.5	0.5	2.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 423 - Enriched 7 mg/dL whole blood						
Fluorometric Manual	79	9.0	0.8	1.1	2.0	0.9
Bacterial Inhibition (Guthrie)	92	8.0	0.8	1.2	1.8	0.9
Fluor Cont Flo, In house	16	11.2	0.5	0.5	2.4	1.2
Fluor Cont Flo, Kit	100	9.7	1.1	1.9	2.1	1.1
Colorimetric	107	10.1	0.9	2.0	1.8	1.1
PerkinElmer Neonatal Fluor	257	8.1	0.8	1.3	1.5	0.9
HPLC	60	8.3	0.6	1.0	1.5	0.9
MS/MS Non-Kit	492	8.3	0.8	1.3	1.5	0.9
MS/MS PE Neogram MS2 Kit	147	8.1	0.9	1.2	1.7	0.9
Neometrics Accuwell	40	9.1	0.6	0.9	1.5	1.1
Bio-Rad Quantase	129	8.1	0.9	1.5	1.2	1.0
MP Biomed (ICN) Enzyme	20	9.5	0.9	2.0	1.6	1.0
Interscientific Enzyme	49	8.4	0.8	0.8	1.5	1.0
Other	30	9.8	1.0	1.3	2.5	1.0
Lot 424 - Nonenriched 11 mg/dL whole blood						
Fluorometric Manual	79	12.2	1.3	1.4	2.0	0.9
Bacterial Inhibition (Guthrie)	90	11.4	1.2	1.5	1.8	0.9
Fluor Cont Flo, In house	16	16.0	1.5	1.5	2.4	1.2
Fluor Cont Flo, Kit	99	13.9	1.3	2.5	2.1	1.1
Colorimetric	106	14.2	1.5	3.2	1.8	1.1
PerkinElmer Neonatal Fluor	253	11.4	1.1	1.8	1.5	0.9
HPLC	69	11.5	1.4	1.8	1.5	0.9
MS/MS Non-Kit	489	11.8	1.1	1.8	1.5	0.9
MS/MS PE Neogram MS2 Kit	146	11.4	1.0	1.6	1.7	0.9
Neometrics Accuwell	39	13.7	0.9	1.0	1.5	1.1
Bio-Rad Quantase	126	12.1	1.3	1.5	1.2	1.0
MP Biomed (ICN) Enzyme	20	12.6	0.9	2.6	1.6	1.0
Interscientific Enzyme	49	11.9	0.7	0.9	1.5	1.0
Other	30	13.6	1.0	1.9	2.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9f. 2004 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	39	1.9	0.6	1.1	1.9	0.9
HPLC	40	2.3	0.3	0.3	2.4	1.1
MS/MS Non-Kit	310	2.8	0.4	0.8	2.7	0.9
MS/MS PE Neogram MS2 Kit	48	2.8	0.4	0.5	2.7	0.9
Other	20	5.0	0.5	2.5	4.5	1.5
Lot 322 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	50	4.6	0.9	1.3	1.9	0.9
HPLC	39	5.5	0.6	0.6	2.4	1.1
MS/MS Non-Kit	310	5.4	0.6	1.3	2.7	0.9
MS/MS PE Neogram MS2 Kit	49	5.1	0.5	0.7	2.7	0.9
Other	20	8.4	0.5	3.5	4.5	1.5
Lot 323 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	49	8.7	1.1	1.8	1.9	0.9
HPLC	39	10.0	2.1	2.1	2.4	1.1
MS/MS Non-Kit	302	9.5	1.0	2.3	2.7	0.9
MS/MS PE Neogram MS2 Kit	49	8.9	0.9	1.2	2.7	0.9
Other	19	14.5	0.9	6.0	4.5	1.5
Lot 324 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	46	12.2	2.2	3.3	1.9	0.9
HPLC	39	13.8	1.2	2.3	2.4	1.1
MS/MS Non-Kit	313	13.0	1.2	3.0	2.7	0.9
MS/MS PE Neogram MS2 Kit	51	12.0	1.3	1.4	2.7	0.9
Other	20	21.0	1.3	9.8	4.5	1.5

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	50	2.2	0.7	1.0	2.2	0.8
HPLC	59	2.0	0.3	0.4	2.1	1.0
MS/MS Non-Kit	717	2.4	0.3	0.6	2.4	0.9
MS/MS PE Neogram MS2 Kit	168	2.2	0.3	0.4	2.2	0.8
Other	57	3.0	0.7	0.8	3.0	1.2
Lot 326 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	77	4.6	1.0	1.8	2.2	0.8
HPLC	60	5.1	0.4	0.6	2.1	1.0
MS/MS Non-Kit	720	5.2	0.6	1.1	2.4	0.9
MS/MS PE Neogram MS2 Kit	167	4.7	0.5	0.7	2.2	0.8
Other	59	6.6	1.2	1.8	3.0	1.2
Lot 327 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	76	8.1	2.1	3.3	2.2	0.8
HPLC	58	9.0	0.9	1.4	2.1	1.0
MS/MS Non-Kit	719	8.8	1.0	1.9	2.4	0.9
MS/MS PE Neogram MS2 Kit	165	7.9	0.9	1.2	2.2	0.8
Other	60	11.5	1.2	3.3	3.0	1.2
Lot 328 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	69	11.2	1.9	2.6	2.2	0.8
HPLC	58	13.1	1.6	2.5	2.1	1.0
MS/MS Non-Kit	719	12.7	1.6	3.0	2.4	0.9
MS/MS PE Neogram MS2 Kit	167	11.3	1.1	1.7	2.2	0.8
Other	60	16.5	1.8	5.5	3.0	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	1.8	0.4	0.4	1.6	0.8
HPLC	19	1.9	0.6	0.6	2.1	0.8
MS/MS Non-Kit	417	2.4	0.3	0.6	2.4	1.0
MS/MS PE Neogram MS2 Kit	146	2.3	0.2	0.5	2.3	0.9
Other	40	3.4	0.7	1.5	3.3	1.2
Lot 422 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	29	4.0	1.2	1.2	1.6	0.8
HPLC	19	4.6	0.7	0.7	2.1	0.8
MS/MS Non-Kit	413	5.1	0.5	1.1	2.4	1.0
MS/MS PE Neogram MS2 Kit	148	4.9	0.5	0.8	2.3	0.9
Other	40	6.6	0.6	2.3	3.3	1.2
Lot 423 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	28	6.6	1.6	1.6	1.6	0.8
HPLC	20	8.6	2.0	2.0	2.1	0.8
MS/MS Non-Kit	415	10.1	1.0	2.3	2.4	1.0
MS/MS PE Neogram MS2 Kit	148	9.2	0.8	1.3	2.3	0.9
Other	40	12.4	1.2	4.8	3.3	1.2
Lot 424 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	30	10.4	3.4	4.1	1.6	0.8
HPLC	20	10.8	2.1	2.7	2.1	0.8
MS/MS Non-Kit	416	13.0	1.4	3.1	2.4	1.0
MS/MS PE Neogram MS2 Kit	148	12.0	1.1	1.6	2.3	0.9
Other	40	16.5	1.5	6.6	3.3	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9g. 2004 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	30	0.5	0.3	0.6	0.8	1.3
HPLC	39	0.2	0.1	0.1	0.2	0.9
MS/MS Non-Kit	317	0.4	0.1	0.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	38	0.5	0.2	0.3	0.5	0.9
Lot 322 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	40	2.2	0.8	1.2	0.8	1.3
HPLC	40	1.1	0.1	0.2	0.2	0.9
MS/MS Non-Kit	315	1.3	0.2	0.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	1.3	0.1	0.2	0.5	0.9
Lot 323 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	40	5.2	1.3	2.0	0.8	1.3
HPLC	39	3.2	0.3	0.6	0.2	0.9
MS/MS Non-Kit	313	3.1	0.4	0.6	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	3.2	0.4	0.4	0.5	0.9
Lot 324 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	39	8.3	1.7	2.9	0.8	1.3
HPLC	40	5.8	0.5	0.8	0.2	0.9
MS/MS Non-Kit	315	5.8	0.5	1.0	0.4	0.9
MS/MS PE Neogram MS2 Kit	40	5.9	0.7	0.7	0.5	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	0.6	0.3	0.8	1.1	1.1
HPLC	59	0.4	0.3	0.1	0.3	0.9
MS/MS Non-Kit	718	0.4	0.3	0.1	0.4	0.9
MS/MS PE Neogram MS2 Kit	163	0.5	0.3	0.1	0.5	0.9
Lot 326 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	50	2.2	0.7	1.1	1.1	1.1
HPLC	60	1.2	0.2	0.3	0.3	0.9
MS/MS Non-Kit	731	1.3	0.2	0.3	0.4	0.9
MS/MS PE Neogram MS2 Kit	165	1.4	0.2	0.3	0.5	0.9
Lot 327 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	49	4.5	1.5	2.6	1.1	1.1
HPLC	60	2.9	0.2	0.5	0.3	0.9
MS/MS Non-Kit	733	3.0	0.5	0.7	0.4	0.9
MS/MS PE Neogram MS2 Kit	164	3.1	0.3	0.5	0.5	0.9
Lot 328 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	39	7.2	2.9	3.4	1.1	1.1
HPLC	60	5.7	0.5	1.0	0.3	0.9
MS/MS Non-Kit	731	5.8	0.6	1.0	0.4	0.9
MS/MS PE Neogram MS2 Kit	167	5.7	0.7	1.0	0.5	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays		Inequalities Were Reported				
HPLC	20	0.3	0.1	0.1	0.2	0.8
MS/MS Non-Kit	412	0.4	0.3	0.3	0.4	0.9
MS/MS PE Neogram MS2 Kit	149	0.5	0.1	0.1	0.4	1.0
Lot 422 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	20	2.0	0.6	0.6	0.7	1.2
HPLC	20	1.1	0.2	0.2	0.2	0.8
MS/MS Non-Kit	415	1.2	0.2	0.3	0.4	0.9
MS/MS PE Neogram MS2 Kit	146	1.4	0.2	0.3	0.4	1.0
Lot 423 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	20	4.2	1.3	1.3	0.7	1.2
HPLC	18	2.5	0.5	0.6	0.2	0.8
MS/MS Non-Kit	414	3.0	0.3	0.6	0.4	0.9
MS/MS PE Neogram MS2 Kit	150	3.3	0.4	0.7	0.4	1.0
Lot 424 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	19	8.2	2.2	3.1	0.7	1.2
HPLC	19	5.4	1.1	1.2	0.2	0.8
MS/MS Non-Kit	412	5.9	0.6	1.2	0.4	0.9
MS/MS PE Neogram MS2 Kit	149	6.5	0.8	1.2	0.4	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9h. 2004 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL whole blood						
HPLC	58	1.2	0.2	0.4	1.3	1.0
MS/MS Non-Kit	308	1.2	0.1	0.3	1.2	0.9
MS/MS PE Neogram MS2 Kit	49	1.3	0.2	0.3	1.3	0.9
Other	39	1.8	0.3	0.5	1.9	1.0
Lot 322 - Enriched 2 mg/dL whole blood						
HPLC	70	2.2	0.3	0.5	1.3	1.0
MS/MS Non-Kit	319	2.1	0.2	0.5	1.2	0.9
MS/MS PE Neogram MS2 Kit	48	2.1	0.3	0.4	1.3	0.9
Other	39	2.9	0.3	0.6	1.9	1.0
Lot 323 - Enriched 3 mg/dL whole blood						
HPLC	61	4.3	0.4	0.9	1.3	1.0
MS/MS Non-Kit	340	4.0	0.5	0.8	1.2	0.9
MS/MS PE Neogram MS2 Kit	50	4.3	0.5	0.7	1.3	0.9
Other	40	5.0	0.4	0.9	1.9	1.0
Lot 324 - Enriched 8 mg/dL whole blood						
HPLC	70	8.9	0.7	1.5	1.3	1.0
MS/MS Non-Kit	320	8.5	0.9	1.9	1.2	0.9
MS/MS PE Neogram MS2 Kit	49	8.6	1.3	1.6	1.3	0.9
Other	40	10.0	0.9	1.9	1.9	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TYROSINE (mg Tyr/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 - Nonenriched 0 mg/dL whole blood						
HPLC	105	1.3	0.2	0.4	1.3	0.9
MS/MS Non-Kit	717	1.3	0.2	0.3	1.3	0.9
MS/MS PE Neogram MS2 Kit	175	1.3	0.2	0.2	1.3	0.9
Other	80	1.9	0.2	0.5	1.9	1.1
Lot 326 - Enriched 1 mg/dL whole blood						
HPLC	129	2.3	0.2	0.4	1.3	0.9
MS/MS Non-Kit	732	2.2	0.3	0.4	1.3	0.9
MS/MS PE Neogram MS2 Kit	175	2.3	0.3	0.3	1.3	0.9
Other	79	3.1	0.3	0.7	1.9	1.1
Lot 327 - Enriched 3 mg/dL whole blood						
HPLC	108	4.2	0.4	0.7	1.3	0.9
MS/MS Non-Kit	708	4.0	0.5	0.7	1.3	0.9
MS/MS PE Neogram MS2 Kit	172	4.1	0.5	0.6	1.3	0.9
Other	80	5.0	0.5	0.9	1.9	1.1
Lot 328 - Enriched 8 mg/dL whole blood						
HPLC	130	8.7	0.7	1.5	1.3	0.9
MS/MS Non-Kit	729	8.6	1.0	1.6	1.3	0.9
MS/MS PE Neogram MS2 Kit	178	8.7	0.9	1.2	1.3	0.9
Other	80	10.6	1.3	1.8	1.9	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TYROSINE (mg Tyr/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
HPLC	49	1.2	0.2	0.3	1.3	0.9
MS/MS Non-Kit	410	1.3	0.2	0.3	1.2	0.9
MS/MS PE Neogram MS2 Kit	149	1.4	0.1	0.2	1.3	0.9
Other	40	2.1	0.2	0.6	1.9	1.1
Lot 422 - Enriched 1 mg/dL whole blood						
HPLC	60	2.2	0.3	0.3	1.3	0.9
MS/MS Non-Kit	412	2.2	0.3	0.4	1.2	0.9
MS/MS PE Neogram MS2 Kit	148	2.3	0.3	0.4	1.3	0.9
Other	39	3.1	0.4	0.6	1.9	1.1
Lot 423 - Enriched 3 mg/dL whole blood						
HPLC	47	3.9	0.4	0.5	1.3	0.9
MS/MS Non-Kit	412	4.0	0.5	0.8	1.2	0.9
MS/MS PE Neogram MS2 Kit	148	4.1	0.4	0.6	1.3	0.9
Other	40	5.1	0.3	0.6	1.9	1.1
Lot 424 - Enriched 8 mg/dL whole blood						
HPLC	59	8.4	0.9	1.5	1.3	0.9
MS/MS Non-Kit	411	8.6	1.0	1.7	1.2	0.9
MS/MS PE Neogram MS2 Kit	149	8.9	0.8	1.3	1.3	0.9
Other	40	11.1	1.0	1.4	1.9	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9i. 2004 Quality Control Data
Summaries of Statistical Analyses

VALINE (mg Val/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 - Nonenriched 0 mg/dL whole blood						
HPLC	30	2.1	0.2	0.5	2.0	1.0
MS/MS Non-Kit	262	2.0	0.2	0.6	1.9	0.8
MS/MS PE Neogram MS2 Kit	40	2.0	0.3	0.3	1.9	0.8
Lot 322 - Enriched 1 mg/dL whole blood						
HPLC	30	2.9	0.2	0.5	2.0	1.0
MS/MS Non-Kit	272	2.6	0.3	0.8	1.9	0.8
MS/MS PE Neogram MS2 Kit	40	2.5	0.3	0.4	1.9	0.8
Lot 323 - Enriched 3 mg/dL whole blood						
HPLC	30	5.0	0.3	0.8	2.0	1.0
MS/MS Non-Kit	272	4.2	0.5	1.2	1.9	0.8
MS/MS PE Neogram MS2 Kit	40	4.4	0.5	0.7	1.9	0.8
Lot 324 - Enriched 6 mg/dL whole blood						
HPLC	30	7.9	0.4	1.3	2.0	1.0
MS/MS Non-Kit	276	6.6	0.7	1.9	1.9	0.8
MS/MS PE Neogram MS2 Kit	39	6.6	0.8	1.0	1.9	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

VALINE (mg Val/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 Nonenriched 0 mg/dL whole blood						
HPLC	50	2.2	0.3	0.5	2.3	0.9
MS/MS Non-Kit	597	2.0	0.3	0.5	2.0	0.7
MS/MS PE Neogram MS2 Kit	158	1.9	0.2	0.4	2.0	0.7
Lot 326 - Enriched 1 mg/dL whole blood						
HPLC	50	3.3	0.3	0.6	2.3	0.9
MS/MS Non-Kit	597	2.8	0.4	0.8	2.0	0.7
MS/MS PE Neogram MS2 Kit	158	2.7	0.3	0.5	2.0	0.7
Lot 327 - Enriched 3 mg/dL whole blood						
HPLC	50	5.1	0.3	0.8	2.3	0.9
MS/MS Non-Kit	597	4.2	0.5	1.1	2.0	0.7
MS/MS PE Neogram MS2 Kit	155	4.2	0.5	0.9	2.0	0.7
Lot 328 - Enriched 6 mg/dL whole blood						
HPLC	49	7.9	0.8	1.4	2.3	0.9
MS/MS Non-Kit	592	6.5	0.7	1.7	2.0	0.7
MS/MS PE Neogram MS2 Kit	156	6.4	0.7	1.2	2.0	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

VALINE (mg Val/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 Nonenriched 0 mg/dL whole blood						
HPLC	20	2.1	0.2	0.3	2.2	0.8
MS/MS Non-Kit	332	2.1	0.2	0.6	2.0	0.8
MS/MS PE Neogram MS2 Kit	137	2.0	0.2	0.4	2.0	0.9
Lot 422 - Enriched 1 mg/dL whole blood						
HPLC	20	3.1	0.4	0.4	2.2	0.8
MS/MS Non-Kit	316	2.9	0.4	0.8	2.0	0.8
MS/MS PE Neogram MS2 Kit	135	2.9	0.3	0.6	2.0	0.9
Lot 423 - Enriched 3 mg/dL whole blood						
HPLC	19	4.4	0.7	0.7	2.2	0.8
MS/MS Non-Kit	334	4.2	0.5	1.1	2.0	0.8
MS/MS PE Neogram MS2 Kit	137	4.3	0.5	1.0	2.0	0.9
Lot 424 - Enriched 6 mg/dL whole blood						
HPLC	20	7.0	0.6	1.4	2.2	0.8
MS/MS Non-Kit	333	6.9	0.8	1.9	2.0	0.8
MS/MS PE Neogram MS2 Kit	138	7.2	0.8	1.5	2.0	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9j. 2004 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (mg Cit/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 321 Nonenriched 0 mg/dL whole blood						
MS/MS Non-Kit	270	0.5	0.1	0.3	0.5	0.8
MS/MS PE Neogram MS2 Kit	40	0.5	0.0	0.1	0.5	0.9
Lot 322 - Enriched 0.5 mg/dL whole blood						
MS/MS Non-Kit	270	0.9	0.3	0.6	0.5	0.8
MS/MS PE Neogram MS2 Kit	40	1.0	0.1	0.2	0.5	0.9
Lot 323 - Enriched 1 mg/dL whole blood						
MS/MS Non-Kit	269	1.3	0.4	0.9	0.5	0.8
MS/MS PE Neogram MS2 Kit	40	1.5	0.2	0.2	0.5	0.9
Lot 324 - Enriched 2.5 mg/dL whole blood						
MS/MS Non-Kit	271	2.5	0.5	1.4	0.5	0.8
MS/MS PE Neogram MS2 Kit	40	2.8	0.2	0.5	0.5	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

CITRULLINE (mg Cit/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 325 Nonenriched 0 mg/dL whole blood						
MS/MS Non-Kit	615	0.5	0.2	0.3	0.5	0.8
MS/MS PE Neogram MS2 Kit	167	0.6	0.1	0.1	0.6	1.0
Lot 326 - Enriched 0.5 mg/dL whole blood						
MS/MS Non-Kit	622	0.9	0.2	0.5	0.5	0.8
MS/MS PE Neogram MS2 Kit	168	1.1	0.1	0.2	0.6	1.0
Lot 327 - Enriched 1 mg/dL whole blood						
MS/MS Non-Kit	618	1.3	0.4	0.8	0.5	0.8
MS/MS PE Neogram MS2 Kit	166	1.6	0.4	0.4	0.6	1.0
Lot 328 - Enriched 2.5 mg/dL whole blood						
MS/MS Non-Kit	619	2.5	0.7	1.5	0.5	0.8
MS/MS PE Neogram MS2 Kit	168	3.0	0.3	0.4	0.6	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

CITRULLINE (mg Cit/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 Nonenriched 0 mg/dL whole blood						
MS/MS Non-Kit	355	0.5	0.1	0.2	0.5	0.7
MS/MS PE Neogram MS2 Kit	149	0.6	0.1	0.1	0.6	0.9
Lot 422 - Enriched 0.5 mg/dL whole blood						
MS/MS Non-Kit	355	0.8	0.2	0.4	0.5	0.7
MS/MS PE Neogram MS2 Kit	151	1.1	0.1	0.2	0.6	0.9
Lot 423 - Enriched 1 mg/dL whole blood						
MS/MS Non-Kit	358	1.2	0.2	0.6	0.5	0.7
MS/MS PE Neogram MS2 Kit	152	1.5	0.1	0.2	0.6	0.9
Lot 424 - Enriched 2.5 mg/dL whole blood						
MS/MS Non-Kit	352	2.2	0.5	1.2	0.5	0.7
MS/MS PE Neogram MS2 Kit	152	3.0	0.2	0.4	0.6	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9k. 2004 Quality Control Data
Summaries of Statistical Analyses

ACETYLCARNITINE (µmol C2/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	360	12.06	2.82	5.19	11.75	1.15
MS/MS PE Neogram MS2 Kit	50	13.79	1.75	5.22	13.60	0.83
Lot 362 - Enriched 5 µmol/L whole blood						
MS/MS Non-Kit	361	17.07	3.08	5.96	11.75	1.15
MS/MS PE Neogram MS2 Kit	50	17.38	1.68	4.56	13.60	0.83
Lot 363 - Enriched 10 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	365	23.26	3.80	7.23	11.75	1.15
MS/MS PE Neogram MS2 Kit	50	22.01	2.86	4.32	13.60	0.83
Lot 364 - Enriched 20 µmol/L whole blood						
MS/MS Non-Kit	370	34.84	5.34	9.99	11.75	1.15
MS/MS PE Neogram MS2 Kit	50	30.12	2.78	5.77	13.60	0.83

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ACETYLCARNITINE (µmol C2/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	839	22.77	4.36	8.06	23.39	0.84
MS/MS PE Neogram MS2 Kit	205	22.67	3.22	4.97	23.55	0.63
Lot 366 - Enriched 5 µmol/L whole blood						
MS/MS Non-Kit	834	27.66	4.25	8.83	23.39	0.84
MS/MS PE Neogram MS2 Kit	208	27.14	3.63	5.09	23.55	0.63
Lot 367 - Enriched 10 µmol/L whole blood						
MS/MS Non-Kit	822	32.94	5.17	9.89	23.39	0.84
MS/MS PE Neogram MS2 Kit	206	30.85	3.30	5.85	23.55	0.63
Lot 368 - Enriched 20 µmol/L whole blood						
MS/MS Non-Kit	829	39.56	6.08	11.28	23.39	0.84
MS/MS PE Neogram MS2 Kit	204	35.40	3.84	7.79	23.55	0.63

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ACETYLCARNITINE (µmol C2/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	480	25.06	3.78	10.10	23.29	0.76
MS/MS PE Neogram MS2 Kit	167	25.87	2.98	5.32	24.07	0.58
Lot 462 - Enriched 5 µmol/L whole blood						
MS/MS Non-Kit	480	26.53	3.69	9.64	23.29	0.76
MS/MS PE Neogram MS2 Kit	167	26.45	2.43	4.42	24.07	0.58
Lot 463 - Enriched 10 µmol/L whole blood						
MS/MS Non-Kit	479	28.23	4.25	10.11	23.29	0.76
MS/MS PE Neogram MS2 Kit	167	26.98	2.78	4.69	24.07	0.58
Lot 464 - Enriched 20 µmol/L whole blood						
MS/MS Non-Kit	470	40.05	5.14	10.15	23.29	0.76
MS/MS PE Neogram MS2 Kit	167	37.15	3.76	8.40	24.07	0.58

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9l. 2004 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE (µmol C3/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	389	0.80	0.16	0.23	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	0.79	0.08	0.10	0.55	1.13
Lot 362 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	390	3.89	0.58	0.84	0.65	1.14
MS/MS PE Neogram MS2 Kit	50	3.71	0.33	0.42	0.55	1.13
Lot 363 - Enriched 7.5 µmol/L whole blood						
MS/MS Non-Kit	405	9.14	1.53	2.09	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	8.91	0.88	1.14	0.55	1.13
Lot 364 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	400	14.37	2.32	3.06	0.65	1.14
MS/MS PE Neogram MS2 Kit	49	14.30	1.36	1.86	0.55	1.13

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PROPIONYLCARNITINE (µmol C3/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	906	1.57	0.32	0.40	1.71	1.12
MS/MS PE Neogram MS2 Kit	210	1.65	0.35	0.43	1.79	1.17
Lot 366 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	899	5.19	0.78	1.05	1.71	1.12
MS/MS PE Neogram MS2 Kit	206	5.35	0.59	0.91	1.79	1.17
Lot 367 - Enriched 7.5 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	894	10.30	2.23	2.69	1.71	1.12
MS/MS PE Neogram MS2 Kit	205	10.84	0.98	1.77	1.79	1.17
Lot 368 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	915	15.03	2.49	3.31	1.71	1.12
MS/MS PE Neogram MS2 Kit	214	15.62	1.62	2.50	1.79	1.17

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PROPIONYLCARNITINE (µmol C3/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	519	2.19	0.37	0.52	1.95	1.13
MS/MS PE Neogram MS2 Kit	171	2.31	0.28	0.44	1.96	1.25
Lot 462 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	523	5.09	0.69	1.07	1.95	1.13
MS/MS PE Neogram MS2 Kit	169	5.39	0.48	0.76	1.96	1.25
Lot 463 - Enriched 7.5 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	525	10.23	1.42	2.27	1.95	1.13
MS/MS PE Neogram MS2 Kit	170	11.05	1.04	1.64	1.96	1.25
Lot 464 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	527	15.64	2.08	3.36	1.95	1.13
MS/MS PE Neogram MS2 Kit	167	17.27	1.71	2.48	1.96	1.25

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9m. 2004 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE (μmol C4/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 μmol/L whole blood						
MS/MS Non-Kit	409	0.16	0.11	0.17	0.08	1.02
MS/MS PE Neogram MS2 Kit	50	0.15	0.03	0.05	0.04	1.04
Lot 362 - Enriched 1 μmol/L whole blood						
MS/MS Non-Kit	402	0.98	0.19	0.35	0.08	1.02
MS/MS PE Neogram MS2 Kit	50	0.96	0.12	0.17	0.04	1.04
Lot 363 - Enriched 2.5 μmol/L whole blood						
MS/MS Non-Kit	409	2.67	0.36	0.74	0.08	1.02
MS/MS PE Neogram MS2 Kit	49	2.60	0.44	0.63	0.04	1.04
Lot 364 - Enriched 5 μmol/L whole blood						
MS/MS Non-Kit	395	5.18	0.69	1.40	0.08	1.02
MS/MS PE Neogram MS2 Kit	54	5.28	0.67	0.87	0.04	1.04

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

BUTYRYLCARNITINE (µmol C4/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	891	0.23	0.12	0.17	0.30	0.91
MS/MS PE Neogram MS2 Kit	206	0.23	0.08	0.08	0.31	0.87
Lot 366 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	911	1.22	0.24	0.31	0.30	0.91
MS/MS PE Neogram MS2 Kit	205	1.20	0.28	0.34	0.31	0.87
Lot 367 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	908	2.67	0.49	0.65	0.30	0.91
MS/MS PE Neogram MS2 Kit	206	2.58	0.49	0.61	0.31	0.87
Lot 368 - Enriched 5 µmol/L whole blood						
MS/MS Non-Kit	917	4.79	0.86	1.18	0.30	0.91
MS/MS PE Neogram MS2 Kit	205	4.59	0.94	1.19	0.31	0.87

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

BUTYRYLCARNITINE (µmol C4/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	490	0.29	0.09	0.13	0.24	0.86
MS/MS PE Neogram MS2 Kit	164	0.33	0.12	0.13	0.24	0.90
Lot 462 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	498	1.11	0.21	0.30	0.24	0.86
MS/MS PE Neogram MS2 Kit	168	1.16	0.27	0.31	0.24	0.90
Lot 463 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	495	2.28	0.34	0.62	0.24	0.86
MS/MS PE Neogram MS2 Kit	169	2.29	0.43	0.60	0.24	0.90
Lot 464 - Enriched 5 µmol/L whole blood						
MS/MS Non-Kit	490	4.61	0.62	1.06	0.24	0.86
MS/MS PE Neogram MS2 Kit	164	4.84	0.96	1.16	0.24	0.90

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9n. 2004 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE (µmol C5/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	404	0.12	0.05	0.14	0.09	1.00
MS/MS PE Neogram MS2 Kit	50	0.15	0.05	0.09	0.12	0.97
Lot 362 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	391	0.57	0.12	0.24	0.09	1.00
MS/MS PE Neogram MS2 Kit	48	0.56	0.12	0.17	0.12	0.97
Lot 363 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	415	1.58	0.33	0.56	0.09	1.00
MS/MS PE Neogram MS2 Kit	52	1.57	0.23	0.28	0.12	0.97
Lot 364 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	402	3.11	0.45	0.94	0.09	1.00
MS/MS PE Neogram MS2 Kit	46	3.05	0.46	0.57	0.12	0.97

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ISOVALERYLCARNITINE (µmol C5/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	881	0.15	0.06	0.11	0.17	1.03
MS/MS PE Neogram MS2 Kit	197	0.18	0.11	0.12	0.21	1.03
Lot 366 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	885	0.70	0.14	0.20	0.17	1.03
MS/MS PE Neogram MS2 Kit	195	0.72	0.16	0.17	0.21	1.03
Lot 367 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	862	1.72	0.33	0.50	0.17	1.03
MS/MS PE Neogram MS2 Kit	198	1.81	0.35	0.43	0.21	1.03
Lot 368 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	894	3.25	0.58	0.87	0.17	1.03
MS/MS PE Neogram MS2 Kit	199	3.26	0.62	0.73	0.21	1.03

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ISOVALERYLCARNITINE (µmol C5/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	496	0.20	0.07	0.10	0.17	1.05
MS/MS PE Neogram MS2 Kit	157	0.21	0.07	0.09	0.19	1.12
Lot 462 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	510	0.67	0.30	0.32	0.17	1.05
MS/MS PE Neogram MS2 Kit	155	0.70	0.15	0.19	0.19	1.12
Lot 463 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	502	1.72	0.25	0.41	0.17	1.05
MS/MS PE Neogram MS2 Kit	157	1.88	0.29	0.38	0.19	1.12
Lot 464 - Enriched 3 µmol/L whole blood						
MS/MS Non-Kit	492	3.32	0.46	0.82	0.17	1.05
MS/MS PE Neogram MS2 Kit	155	3.54	0.48	0.70	0.19	1.12

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9o. 2004 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE (µmol C5DC/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - CDC Assayed 0.07 µmol/L whole blood						
MS/MS Non-Kit	827	0.04	0.04	0.04	-0.04	1.09
MS/MS PE Neogram MS2 Kit	188	0.09	0.05	0.08	-0.05	2.12
Lot 366 - CDC Assayed 0.16 µmol/L whole blood						
MS/MS Non-Kit	818	0.13	0.05	0.07	-0.04	1.09
MS/MS PE Neogram MS2 Kit	189	0.29	0.10	0.20	-0.05	2.12
Lot 367 - CDC Assayed 0.25 µmol/L whole blood						
MS/MS Non-Kit	805	0.24	0.06	0.10	-0.04	1.09
MS/MS PE Neogram MS2 Kit	182	0.48	0.23	0.38	-0.05	2.12
Lot 368 - CDC Assayed 0.41 µmol/L whole blood						
MS/MS Non-Kit	801	0.41	0.10	0.18	-0.04	1.09
MS/MS PE Neogram MS2 Kit	186	0.81	0.38	0.60	-0.05	2.12

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d_9-C5, d_3-C8, d_3-C10, d_3-C12, d_3-C16, or d_6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus CDC assayed concentrations and extrapolating the regression to the Y-axis.

GLUTARYLCARNITINE (µmol C5DC/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - CDC Assayed 0.07 µmol/L whole blood						
MS/MS Non-Kit	475	0.04	0.04	0.06	-0.01	0.74
MS/MS PE Neogram MS2 Kit	147	0.10	0.03	0.08	-0.03	1.49
Lot 462 - CDC Assayed 0.24 µmol/L whole blood						
MS/MS Non-Kit	482	0.17	0.07	0.09	-0.01	0.74
MS/MS PE Neogram MS2 Kit	146	0.33	0.09	0.22	-0.03	1.49
Lot 463 - CDC Assayed 0.44 µmol/L whole blood						
MS/MS Non-Kit	475	0.30	0.08	0.14	-0.01	0.74
MS/MS PE Neogram MS2 Kit	146	0.59	0.12	0.41	-0.03	1.49
Lot 464 - CDC Assayed 0.78 µmol/L whole blood						
MS/MS Non-Kit	477	0.57	0.13	0.23	-0.01	0.74
MS/MS PE Neogram MS2 Kit	147	1.16	0.20	0.82	-0.03	1.49

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d_9-C5, d_3-C8, d_3-C10, d_3-C12, d_3-C16, or d_6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus CDC assayed concentrations and extrapolating the regression to the Y-axis.

TABLE 9p. 2004 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE (µmol C6/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	394	0.04	0.03	0.05	0.02	0.91
MS/MS PE Neogram MS2 Kit	49	0.13	0.06	0.27	0.09	0.86
Lot 362 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	390	0.44	0.10	0.16	0.02	0.91
MS/MS PE Neogram MS2 Kit	49	0.50	0.11	0.18	0.09	0.86
Lot 363 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	393	0.92	0.14	0.28	0.02	0.91
MS/MS PE Neogram MS2 Kit	49	0.92	0.29	0.32	0.09	0.86
Lot 364 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	393	2.30	0.32	0.57	0.02	0.91
MS/MS PE Neogram MS2 Kit	47	2.26	0.43	0.51	0.09	0.86

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

HEXANOYLCARNITINE (µmol C6/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	887	0.06	0.06	0.09	0.06	0.89
MS/MS PE Neogram MS2 Kit	190	0.11	0.13	0.27	0.11	0.82
Lot 366 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	869	0.50	0.13	0.17	0.06	0.89
MS/MS PE Neogram MS2 Kit	192	0.51	0.13	0.20	0.11	0.82
Lot 367 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	867	0.96	0.21	0.30	0.06	0.89
MS/MS PE Neogram MS2 Kit	190	0.94	0.22	0.29	0.11	0.82
Lot 368 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	900	2.27	0.46	0.66	0.06	0.89
MS/MS PE Neogram MS2 Kit	201	2.17	0.51	0.60	0.11	0.82

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

HEXANOYLCARNITINE (µmol C6/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	489	0.06	0.05	0.10	0.03	0.88
MS/MS PE Neogram MS2 Kit	151	0.08	0.07	0.22	0.08	0.84
Lot 462 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	493	0.45	0.12	0.17	0.03	0.88
MS/MS PE Neogram MS2 Kit	153	0.49	0.14	0.23	0.08	0.84
Lot 463 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	498	0.91	0.18	0.28	0.03	0.88
MS/MS PE Neogram MS2 Kit	158	0.93	0.22	0.30	0.08	0.84
Lot 464 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	498	2.25	0.36	0.57	0.03	0.88
MS/MS PE Neogram MS2 Kit	152	2.17	0.48	0.60	0.08	0.84

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9q. 2004 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE (µmol C8/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	409	0.05	0.04	0.06	0.02	1.03
MS/MS PE Neogram MS2 Kit	65	0.05	0.04	0.06	0.01	1.00
Lot 362 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	410	0.49	0.09	0.12	0.02	1.03
MS/MS PE Neogram MS2 Kit	65	0.44	0.11	0.14	0.01	1.00
Lot 363 - Enriched 1 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	408	1.04	0.23	0.30	0.02	1.03
MS/MS PE Neogram MS2 Kit	63	1.05	0.25	0.29	0.01	1.00
Lot 364 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	404	2.59	0.30	0.46	0.02	1.03
MS/MS PE Neogram MS2 Kit	66	2.52	0.44	0.51	0.01	1.00

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

OCTANOYLCARNITINE (µmol C8/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	963	0.07	0.04	0.05	0.07	1.08
MS/MS PE Neogram MS2 Kit	223	0.07	0.05	0.05	0.09	0.95
Lot 366 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	949	0.63	0.11	0.14	0.07	1.08
MS/MS PE Neogram MS2 Kit	228	0.59	0.14	0.17	0.09	0.95
Lot 367 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	963	1.14	0.20	0.24	0.07	1.08
MS/MS PE Neogram MS2 Kit	231	1.05	0.20	0.25	0.09	0.95
Lot 368 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	980	2.77	0.43	0.56	0.07	1.08
MS/MS PE Neogram MS2 Kit	225	2.46	0.43	0.52	0.09	0.95

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

OCTANOYLCARNITINE (µmol C8/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	560	0.08	0.05	0.06	0.05	1.06
MS/MS PE Neogram MS2 Kit	180	0.07	0.04	0.05	0.05	1.04
Lot 462 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	553	0.54	0.10	0.13	0.05	1.06
MS/MS PE Neogram MS2 Kit	178	0.55	0.13	0.16	0.05	1.04
Lot 463 - Enriched 1 µmol/L whole blood						
MS/MS Non-Kit	558	1.12	0.17	0.23	0.05	1.06
MS/MS PE Neogram MS2 Kit	180	1.08	0.23	0.27	0.05	1.04
Lot 464 - Enriched 2.5 µmol/L whole blood						
MS/MS Non-Kit	558	2.70	0.32	0.50	0.05	1.06
MS/MS PE Neogram MS2 Kit	179	2.65	0.57	0.66	0.05	1.04

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9r. 2004 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE (μmol C10/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 μmol/L whole blood						
MS/MS Non-Kit	881	0.07	0.05	0.07	0.08	1.20
MS/MS PE Neogram MS2 Kit	229	0.07	0.05	0.06	0.09	0.95
Lot 366 - Enriched 0.25 μmol/L whole blood						
MS/MS Non-Kit	886	0.38	0.09	0.12	0.08	1.20
MS/MS PE Neogram MS2 Kit	221	0.32	0.10	0.12	0.09	0.95
Lot 367 - Enriched 0.75 μmol/L whole blood						
MS/MS Non-Kit	863	0.99	0.22	0.31	0.08	1.20
MS/MS PE Neogram MS2 Kit	227	0.83	0.23	0.28	0.09	0.95
Lot 368 - Enriched 1.5 μmol/L whole blood						
MS/MS Non-Kit	888	1.88	0.39	0.56	0.08	1.20
MS/MS PE Neogram MS2 Kit	225	1.49	0.31	0.44	0.09	0.95

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

DECANOYLCARNITINE (µmol C10/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	499	0.08	0.05	0.06	0.06	1.19
MS/MS PE Neogram MS2 Kit	179	0.07	0.05	0.05	0.06	0.94
Lot 462 - Enriched 0.25 µmol/L whole blood						
MS/MS Non-Kit	501	0.34	0.08	0.10	0.06	1.19
MS/MS PE Neogram MS2 Kit	173	0.28	0.08	0.09	0.06	0.94
Lot 463 - Enriched 0.75 µmol/L whole blood						
MS/MS Non-Kit	506	0.93	0.17	0.27	0.06	1.19
MS/MS PE Neogram MS2 Kit	178	0.76	0.16	0.23	0.06	0.94
Lot 464 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	497	1.85	0.31	0.49	0.06	1.19
MS/MS PE Neogram MS2 Kit	177	1.47	0.27	0.41	0.06	0.94

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9s. 2004 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYLCARNITINE (µmol C14/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	400	0.09	0.06	0.09	0.05	0.97
MS/MS PE Neogram MS2 Kit	50	0.08	0.03	0.04	0.04	0.85
Lot 362 - Enriched 0.5 µmol/L whole blood						
MS/MS Non-Kit	401	0.52	0.13	0.19	0.05	0.97
MS/MS PE Neogram MS2 Kit	49	0.46	0.07	0.10	0.04	0.85
Lot 363 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	418	1.46	0.31	0.51	0.05	0.97
MS/MS PE Neogram MS2 Kit	48	1.28	0.19	0.23	0.04	0.85
Lot 364 - Enriched 3.0 µmol/L whole blood						
MS/MS Non-Kit	425	2.99	0.49	0.86	0.05	0.97
MS/MS PE Neogram MS2 Kit	50	2.62	0.33	0.43	0.04	0.85

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

MYRISTOYLCARNITINE (µmol C14/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	882	0.13	0.06	0.08	0.14	0.96
MS/MS PE Neogram MS2 Kit	207	0.11	0.04	0.05	0.13	0.82
Lot 366 - Enriched 0.5 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	875	0.60	0.16	0.20	0.14	0.96
MS/MS PE Neogram MS2 Kit	203	0.53	0.13	0.18	0.13	0.82
Lot 367 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	843	1.61	0.35	0.46	0.14	0.96
MS/MS PE Neogram MS2 Kit	208	1.43	0.25	0.35	0.13	0.82
Lot 368 - Enriched 3.0 µmol/L whole blood						
MS/MS Non-Kit	851	2.99	0.60	0.80	0.14	0.96
MS/MS PE Neogram MS2 Kit	205	2.55	0.38	0.56	0.13	0.82

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

MYRISTOYLCARNITINE (µmol C14/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	478	0.17	0.08	0.10	0.12	0.97
MS/MS PE Neogram MS2 Kit	168	0.14	0.05	0.07	0.11	0.85
Lot 462 - Enriched 0.5 µmol/L whole blood						
Non-Kit MS/MS Non-KIt	484	0.58	0.13	0.17	0.12	0.97
MS/MS PE Neogram MS2 Kit	169	0.51	0.11	0.14	0.11	0.85
Lot 463 - Enriched 1.5 µmol/L whole blood						
MS/MS Non-Kit	479	1.55	0.27	0.37	0.12	0.97
MS/MS PE Neogram MS2 Kit	167	1.38	0.23	0.35	0.11	0.85
Lot 464 - Enriched 3.0 µmol/L whole blood						
MS/MS Non-Kit	480	3.06	0.47	0.69	0.12	0.97
MS/MS PE Neogram MS2 Kit	169	2.68	0.38	0.59	0.11	0.85

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 9t. 2004 Quality Control Data
Summaries of Statistical Analyses

PALMITOYLCARNITINE (µmol C16/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 361 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	406	0.63	0.15	0.26	0.42	0.91
MS/MS PE Neogram MS2 Kit	49	0.66	0.10	0.13	0.39	0.93
Lot 362 - Enriched 4 µmol/L whole blood						
MS/MS Non-Kit	400	3.84	0.53	1.09	0.42	0.91
MS/MS PE Neogram MS2 Kit	49	3.62	0.56	0.70	0.39	0.93
Lot 363 - Enriched 8 µmol/L whole blood						
MS/MS Non-Kit	400	7.60	1.04	2.24	0.42	0.91
MS/MS PE Neogram MS2 Kit	50	7.98	0.98	1.64	0.39	0.93
Lot 364 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	404	11.55	1.40	3.33	0.42	0.91
MS/MS PE Neogram MS2 Kit	51	11.60	1.39	1.95	0.39	0.93

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PALMITOYLCARNITINE (µmol C16/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 365 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	895	1.16	0.35	0.43	1.15	0.93
MS/MS PE Neogram MS2 Kit	210	1.16	0.46	0.54	1.20	0.90
Lot 366 - Enriched 4 µmol/L whole blood						
MS/MS Non-Kit	894	4.87	0.78	1.16	1.15	0.93
MS/MS PE Neogram MS2 Kit	203	4.77	0.73	0.96	1.20	0.90
Lot 367 - Enriched 8 µmol/L whole blood						
MS/MS Non-Kit	876	8.58	1.33	2.15	1.15	0.93
MS/MS PE Neogram MS2 Kit	209	8.55	1.16	1.70	1.20	0.90
Lot 368 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	909	12.31	1.75	2.82	1.15	0.93
MS/MS PE Neogram MS2 Kit	215	11.90	1.60	2.31	1.20	0.90

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PALMITOYLCARNITINE (µmol C16/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 µmol/L whole blood						
MS/MS Non-Kit	483	1.48	0.33	0.57	1.10	0.98
MS/MS PE Neogram MS2 Kit	168	1.48	0.25	0.33	1.11	1.00
Lot 462 - Enriched 4 µmol/L whole blood						
MS/MS Non-Kit	499	4.60	0.64	0.90	1.10	0.98
MS/MS PE Neogram MS2 Kit	168	4.73	0.70	0.99	1.11	1.00
Lot 463 - Enriched 8 µmol/L whole blood						
MS/MS Non-Kit	503	8.68	1.14	1.72	1.10	0.98
MS/MS PE Neogram MS2 Kit	168	8.74	1.17	1.78	1.11	1.00
Lot 464 - Enriched 12 µmol/L whole blood						
MS/MS Non-Kit	494	13.18	1.56	2.71	1.10	0.98
MS/MS PE Neogram MS2 Kit	159	13.49	1.54	2.76	1.11	1.00

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

NOTES

This ***NEWBORN SCREENING QUALITY ASSURANCE PROGRAM*** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.**

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